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DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
PLAINTIFF NATUS MEDICAL INCORPORATED, a Delaware corporation		DEFENDANT INTELLIGENT HEARING SYSTEMS, a Florida corporation
PATENT OR TRADEMARK NO.		DATE OF PATENT OR TRADEMARK
HOLDER OF PATENT OR TRADEMARK		
1	5,601,091	Feb 11, 1997
2	5,916,174	June 29, 1999
3	6,832,663	Dec 21, 2004
4		
5		

CV 10 707 HRL

In the above-entitled case, the following patent(s)/trademark(s) have been included:

DATE INCLUDED	INCLUDED BY <input type="checkbox"/> Amendment <input type="checkbox"/> Answer <input type="checkbox"/> Cross Bill <input type="checkbox"/> Other Pleading		
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK	
1			
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DECISION/JUDGEMENT

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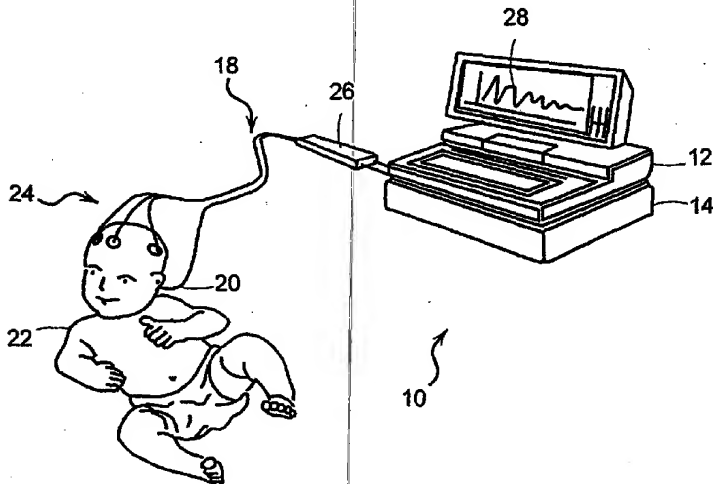
United States Patent [19]**Dolphin**[11] **Patent Number:** **5,601,091**[45] **Date of Patent:** **Feb. 11, 1997**[54] **AUDIOMETRIC APPARATUS AND ASSOCIATION SCREENING METHOD**[75] **Inventor:** William F. Dolphin, Weston, Mass.[73] **Assignee:** Sonamed Corporation, Weston, Mass.[21] **Appl. No.:** 509,836[22] **Filed:** Aug. 1, 1995[51] **Int. Cl.⁵** A61B 5/00[52] **U.S. Cl.** 128/746; 128/731; 73/585[58] **Field of Search** 128/746, 731; 73/585[56] **References Cited****U.S. PATENT DOCUMENTS**

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Primary Examiner—V. Millin**Assistant Examiner**—Robert N. Wieland**Attorney, Agent, or Firm**—Testa, Hurwitz & Thibault, LLP[57] **ABSTRACT**

An audiometric screening apparatus and associated method provides fast, low-cost, noninvasive screening of a subject's hearing. The apparatus includes a signal processor for generating a stimulus signal and a probe electrically coupled to the signal processor and insertible in a subject's ear. The probe includes a transmitter to transmit the stimulus signal into the ear and a receiver for receiving a first response signal from the subject's ear. An electrode, electrically coupled to the signal processor, is attached to the subject's scalp for sensing a second response signal. The signal processor processes the first response signal to provide an evoked otoacoustic emission signal and processes the second response signal to provide an auditory evoked potential signal.

37 Claims, 3 Drawing Sheets

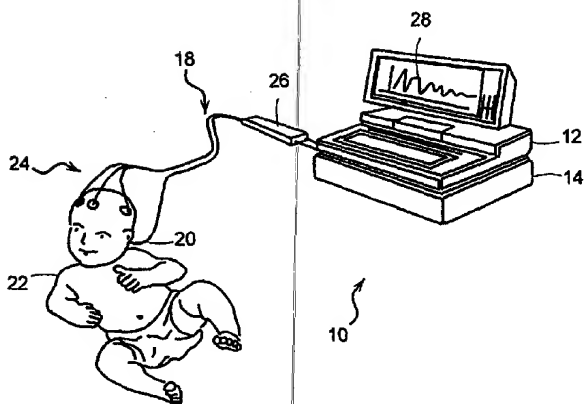


FIG. 1

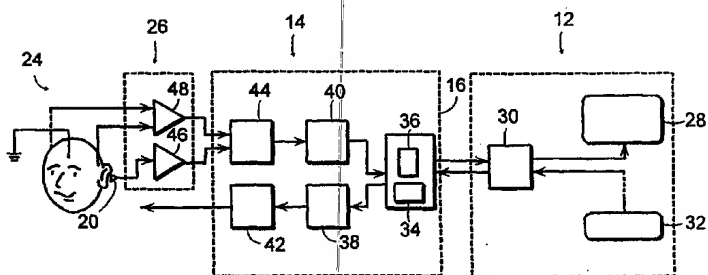


FIG. 2

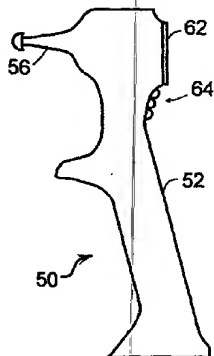


FIG. 3

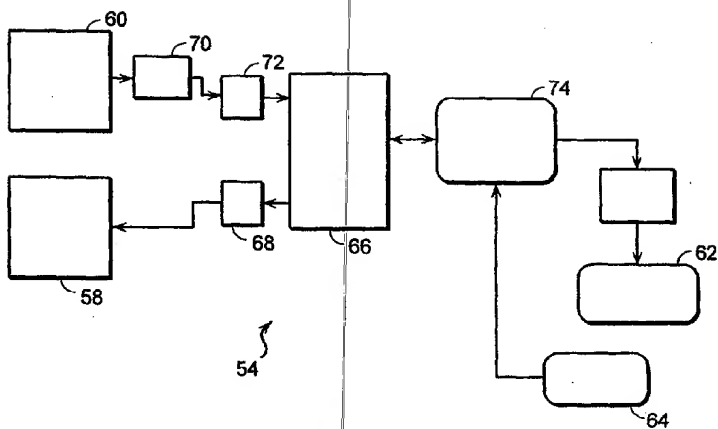


FIG. 4

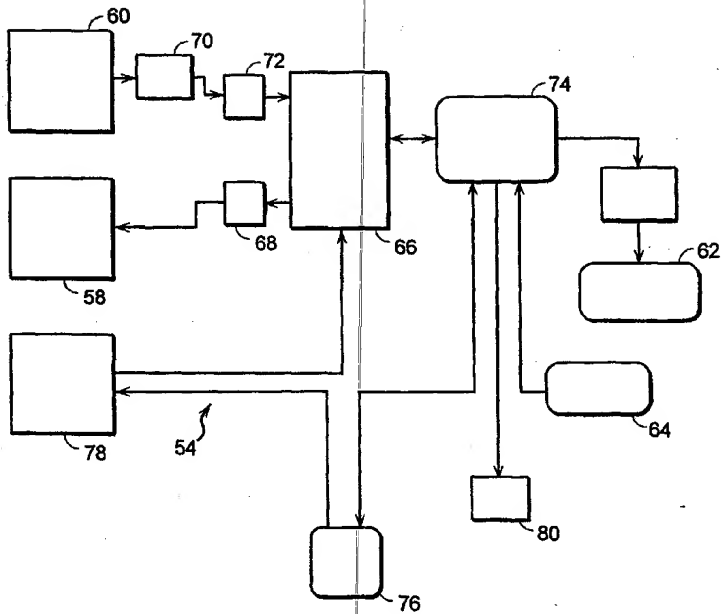


FIG. 5

1 **AUDIOMETRIC APPARATUS AND ASSOCIATION SCREENING METHOD**

BACKGROUND

The present invention relates generally to the field of audiometric apparatuses and associated screening methods. In particular, the invention relates to audiometric apparatuses and auditory screening methods for providing rapid, low-cost, comprehensive, non-invasive screening of a subject's hearing.

Language acquisition in infants requires a critical period of hearing capacity which spans the frequency range of human speech. The critical period extends from birth to about two to three years of age, when infants typically begin to talk with some level of proficiency.

Approximately three to five percent of newborn infants suffer from some degree of hearing impairment. These impairments can be devastating to the social, emotional and intellectual development of the affected infants. Early identification of hearing impairments in infants allows for early intervention to minimize significant speech and language deficiencies. Infants are usually unable or unwilling to participate in known behavioral auditory examinations. Moreover, delaying auditory screening until infants can verbally respond is often too late for hearing impaired infants and results in long term problems.

Federal, state and private agencies have attempted to implement universal auditory screening of infants for over twenty years. A major impediment to the implementation of universal auditory screening of infants has been the cost and complexity associated with the tests. Current infant screening tests are time consuming and require expensive devices and trained specialists to conduct the tests and interpret results. As such, universal auditory screening of infants is presently economically infeasible.

Various entities have developed audiometric devices which may be useable for screening an infant's hearing. These existing devices generally fall into one of two categories. Devices in the first category are configured to elicit auditory evoked potentials (AEPs), which are electrical responses of cells within the auditory pathway of the brain to an acoustic stimulus. Such devices typically utilize the non-invasive auditory brainstem response (ABR) test for auditory screening of infants. An earphone provides an acoustic stimulus, specifically a brief click or toneburst, to the subject's ear. Electrodes attached to the subject's scalp receive auditory evoked potentials from the scalp, which are recorded as an electroencephalogram waveform. Analysis of these brainwave patterns are used to determine if the auditory system is functioning normally.

Devices in the second category utilize the evoked otoacoustic emission (OAE) test for auditory screening. An earphone provides a brief acoustic stimulus to the subject's ear. A microphone disposed in the subject's ear adjacent the earphone receives an OAE from the ear, which is recorded as an acoustic signal. Analysis of the OAE waveform provides an indication of the functional integrity of the middle and inner ear, which together comprise the auditory periphery.

A number of limitations exist with respect to existing audiometric screening devices. One limitation is that some existing devices are complicated and require extensive training to operate. Another limitation is that other devices only provide a pass/fail indication and lack a visual display. Yet another limitation is that two separate devices are required

to perform both the ABR or OAE tests. An operator typically makes a subjective determination of the acceptability of the ABR or OAE test results based on a visual examination of the response waveforms. Because existing audiometric devices do not allow for rapid, low-cost, non-invasive, comprehensive screening of infants, such devices do not adequately address the need for universal auditory infant screening.

2 **SUMMARY OF THE INVENTION**

The present invention contemplates audiometric screening apparatuses and associated methods for providing rapid, low-cost, comprehensive, non-invasive screening of a subject's hearing. An advantage of performing auditory screening using apparatuses incorporating the principles of the invention is that a behavioral response from the subject is not required. Thus, such apparatuses can be used to screen subjects who are unable to respond (e.g., infants) or unwilling or difficult to test (e.g., unconscious or mentally handicapped persons). Another advantage is that the invention is particularly useful in the area of auditory screening of infants. Except for initial infant preparation, the apparatus provides a fully automated screening procedure which includes stimulus presentation, response signal acquisition, signal analysis and interpretation of results. Nurses, technicians or hospital volunteers only require minimal training to perform auditory screening of infants. Thus, the cost of administering such auditory screening tests is reduced, encouraging universal screening of newborn infants.

The invention features an audiometric apparatus for screening a subject's hearing. The apparatus includes a signal processor for generating a first stimulus signal. A probe is electrically coupled to the signal processor and insertible in a subject's ear. The first stimulus signal comprises an amplitude modulated modulated acoustic signal which may include at least one paired tonal stimulus or at least one triple tonal stimulus. The probe includes a transmitter to transmit the first stimulus signal into the ear and a receiver for receiving a first response signal from the subject's ear. At least one electrode, electrically coupled to the signal processor, is attached to the subject's scalp for sensing a second response signal. The signal processor processes the first response signal to provide an OAE signal and processes the second response signal to provide an AEP signal. The signal processor processes the first and second signals in parallel. Moreover, the signal processor may process signals simultaneously to provide simultaneous OAE and AEP signals.

An input device is electrically coupled to a control processor to enable a user to request the signal processor to perform OAE and AEP tests. A display is electrically coupled to the control processor for displaying one or more characteristics of the OAE and AEP signals.

The apparatus may further include the capability to perform acoustic reflectivity (AR) tests. Such tests measure the degree to which sound across a range of frequencies is reflected off of the tympanum. The signal processor generates a second stimulus signal which is transmitted into the subject's ear by the transmitter. The receiver receives a third response signal from the subject's ear, and the signal processor processes the third response signal to provide an AR signal. The AR signal indicates the presence of fluid in the middle ear cavity and other pathologies.

The invention also features a portable audiometric apparatus for screening a subject's hearing. The portable apparatus includes a hand held housing and a docking station for

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receiving the housing. The docking station includes a battery charger for recharging the signal processor and a printer. A signal processor disposed within the housing generates a first stimulus signal. The first stimulus signal comprises an amplitude modulated signal, which may include at least one paired tonal stimulus or at least one triple tonal stimulus. A probe, electrically coupled to the signal processor, extends from the housing and is insertible into a subject's ear. The probe includes a transmitter to transmit the first stimulus signal into the ear and a receiver for receiving a first and second response signals from the subject's ear. The signal processor processes the first response signal to provide an OAE signal and processes the second response signal to provide an auditory indication signal. The auditory indication signal may be a tympanometry signal or an AR signal.

An input device electrically coupled to a control processor to enable a user to request the signal processor to perform OAE and auditory indication tests. A display is electrically coupled to the control processor for displaying one or more characteristics of the OAE and auditory indication signals.

The invention also features an auditory screening method for providing comprehensive screening of a subject's hearing. An electrode is attached to a subject's scalp. A probe, including a transmitter and a receiver, is inserted in the subject's ear. A stimulus signal is transmitted into the subject's ear. The stimulus signal comprises an amplitude modulated signal, which may include at least one paired tonal stimulus or at least one triple tonal stimulus. A response signal is received from the subject's ear via the probe. The response signal is averaged over a plurality of intervals to produce a plurality of subaverages. The subaverages are weighted based on a derived estimate of response content and combined to produce an auditory indication signal.

More specifically, the subaverages are inversely weighted based on the variance and content of the response signal. Further, the inversely weighted subaverages are combined according to the following steps: (i) performing a Fourier transform for each subaverage, (ii) determining real and imaginary components of the Fourier transform at specified frequencies, (iii) independently estimating variance of each component, and (iv) determining the probability of an auditory indication signal using an F statistic.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features of the invention are more fully described below in the detailed description and accompanying drawings of which the figures illustrate audiometric apparatuses and methods.

FIG. 1 is an illustration of an audiometric screening apparatus incorporating the principles of the invention.

FIG. 2 is a block diagram of the audiometric screening apparatus shown in FIG. 1.

FIG. 3 is an illustration of a portable audiometric screening apparatus illustrating the principles of the invention.

FIG. 4 is a block diagram of one embodiment of the portable audiometric screening apparatus shown in FIG. 3.

FIG. 5 is a block diagram of another embodiment of the portable audiometric screening apparatus shown in FIG. 3.

DETAILED DESCRIPTION OF THE INVENTION

The invention contemplates audiometric screening apparatuses for providing rapid, low-cost, comprehensive, non-invasive screening of a subject's hearing. Such apparatuses

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provide a fully automated screening procedure including stimulus presentation, response signal acquisition, signal analysis and interpretation of results. Thus, minimally trained personnel can perform auditory screening tests. Moreover, since such apparatuses do not require a behavioral response from the subject, they are particularly useful for screening infants, unconscious persons or mentally handicapped persons.

In one embodiment, an audiometric screening apparatus incorporating the principles of the invention is capable of performing OAE testing, ABR testing and AR testing. OAE tests take advantage of nonlinearities in the healthy auditory system in obtaining OAE signals. The procedure requires that an acoustic stimulus signal be presented to the subject's ear. The acoustic energy is conducted, via structures of the middle ear, to the fluid filled cochlea. Pressure waves propagating within the fluid result in displacements of the basilar membrane. Such displacements cause excitation of inner and outer hair cells. It is believed that, due to active processes primarily associated with length changes in outer hair cells, energy is retransmitted in a retrograde manner out of the cochlea and conducted through the middle ear to the eardrum. This retransmitted energy causes movement of the eardrum which acts as a speaker, producing acoustic energy detectable in the ear canal. Due to nonlinearities of the ear, this retransmitted sound, which is measured as an OAE, occurs at frequencies other than those present in the original stimulus.

The ABR test is a noninvasive procedure in which an acoustic stimulus signal, such as a brief click or toneburst, is presented to the subject's ear. Electrical potentials are recorded from the scalp using electrodes. In a normally functioning auditory system, a suprathreshold sound stimulates cells within the auditory pathway of the brain (primarily neurons comprising the auditory nerve and brainstem structures). This excitation spreads from the peripheral to more central structures resulting in the discharge of large numbers of neurons within the pathway. The neural activity is time-locked to the acoustic stimulus signal resulting in the synchronized discharge of large neuronal assemblies. As excitation moves through the auditory system, a sequential pattern of electrical potentials are measured from the scalp which appear as a highly stereotypical series of waves on an electroencephalogram. Analysis of these acoustically evoked brainwave patterns can be used to determine if the auditory system is functioning normally.

AR tests measure the degree to which sound across a range of frequencies is reflected off of the tympanum. An stimulus signal is transmitted into the subject's ear, and an AR response signal is received therefrom. The AR signal provides an indication of the presence of fluid in the middle ear cavity.

FIG. 1 illustrates an audiometric screening apparatus incorporating the principles of the invention. The apparatus 10 is controlled by a laptop computer 12. The computer is electrically connected to a docking station 14. A signal processor 16 (FIG. 2) disposed in the docking station generates acoustic stimulus signals in response to computer commands. A probe 18 includes an earphone 20 for presenting acoustic stimulus signals generated by the signal processor to the (infant) subject 22. The earphone also receives an OAE response signal from the subject's ear. Electrodes 24 attached to the subject's scalp sensing an ABR response signal. The response signals are amplified in a bioamplifier unit 26 and provided to the signal processor for processing and analysis. One or more characteristics of the processed OAE and AEP signals are displayed on the computer moni-

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tor 28 along with other pertinent information and other middle and inner ear pathologies.

Using a plurality of signal processing algorithms, the processed response signals are analyzed to detect the presence of a response, and, alternatively or additionally, compared with age weighted population normal signals stored in memory. If the processed response signals compare favorably with the population normal signals, the subject "passes" the screening test. If responses deviate from population normal signals by greater than a specified acceptance tolerance, the subject is "referred" for further diagnostic examinations.

The apparatus 10 may further include the capability to perform acoustic reflectivity (AR) tests. Such tests measure the degree to which sound across a range of frequencies is reflected off of the tympanum. The signal processor generates a stimulus signal which is transmitted into the subject's ear by the earphone. A third response signal from the subject's ear is received by the earphone and passed to the signal processor for processing. A processed AR signal, providing an indication the presence of fluid in the middle ear cavity, is displayed on the monitor.

FIG. 2 is a block diagram of the audiometric screening apparatus shown in FIG. 1. The apparatus includes three main components: the computer 12, the docking station 24 and the bioamplifier unit 26. The computer includes the monitor 28, a control processor 30 and a keyboard 32. The docking station includes a signal processor 16 (which includes one or more digital signal processing (DSP) chip 34 and memory 36), analog-to-digital (A/D) converters 38, digital-to-analog (D/A) converters 40, attenuators 42 and filters 44. The bioamplifier unit includes the probe 18 and response signal amplifiers 46 and 48.

The apparatus is controlled by the computer which communicates with the docking station via an ISA bus. A safe connection between the standard 60 Hz wall plug and the docking station is provided by a toroidal isolation transformer (not shown) meeting all UL 544 requirements. In one configuration, the computer includes the following components: an 86-family IBM-compatible processor, 4 MB of memory, a 80 MB hard-drive, and VGA-compatible graphics card and monitor. An operator specifies the test procedure including test type(s), stimulus signal frequencies, intensities, etc. using the keyboard, a mouse or voice input.

The DSP chip 34 digital generates the acoustic stimulus signals used in the auditory tests. In one configuration, the DSP chip is a 32-bit floating point processor and the associated memory 36 includes 4 MB of DRAM. The digital signal generated by the DSP is converted to analog voltage using the (16 bit) D/A converter 38 with two multiplexed channels operating at 500 kHz in single channel mode. The analog signal is passed to the programmable attenuators 42 which have attenuation range of 0.0 to 99.9 dB. The attenuated analog signal is passed to the earphone 20. The analog signal is transmitted by speakers within earphone to stimulate the auditory system of the subject.

In the OAE test, OAE responses to the stimulus signals are detected using a microphone disposed in the earphone. More specifically, the OAEs are evoked using two long duration, simultaneously presented pure tones. The tones are presented at frequencies f_1 and f_2 . In a healthy ear, an analog response signal is remitted from the ear with significant energy at frequency corresponding to the cubic distortion product ($2f_1 - f_2$). In the AEP test, analog response signals are acquired from the scalp are detected using the electrodes 24.

In either case, the response signals from the subject are directed to the bioamplifier unit 26 which complies to

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UL544 and IEC601 standards. The bioamplifier unit is custom designed capable of parallel and simultaneous presentation of two acoustic stimulus signals, acquisition of OAEs from within the ear canal and AEPs from the scalp. The bioamplifier unit is fully programmable, but also has manual controls. Also, the bioamplifier unit includes an impedance meter for testing the electrode impedance used in acquisition of AEPs.

The response signals are amplified in the bioamplifier unit using separate amplifiers 46 and 48 and directed to the docking station. Within the docking station, the signals are passed through anti-aliasing filters 44 and digitized using a 16-bit A/D 40. The digitized signals are written to memory buffers in the signal processor 16, averaged by the DSP chip 34 and uploaded to the computer 12 for storage on a hard drive and display on the monitor 28.

In another embodiment, a portable hand-held audiometric screening apparatus incorporating the principles of the invention is capable of performing OAE testing, AR testing and tympanometry testing. The principles of OAE and AR testing are described above. Tympanometry tests are used to measure the acoustic admittance (or "absorption") of the tympanic membrane and middle ear system at select frequencies over a range of atmospheric pressures. Tympanometry devices typically serve as diagnostic instruments for detecting the presence of fluid in the middle ear cavity.

One primary function of the portable hand-held audiometric screening apparatus is to determine the status of the middle ear, particularly otitis media and collection of fluid in middle ear (middle ear effusion). Such conditions can seriously affect the results of audiometric tests. Middle ear status can be determined by AR otoscopy or tympanometry. It is recommended that an AR or tympanometry test be conducted immediately prior to OAE or ABR testing.

Another primary function of the portable audiometric screening apparatus is to perform OAE tests to determine whether the auditory periphery is functioning normally. In auditory screening of infants, the OAE test may be used with the objective of eliminating all babies with normally functioning auditory peripheries. Those babies that fail the initial test may be rescreened using other diagnostic tests.

FIG. 3 illustrates a portable audiometric apparatus for screening a subject's hearing. The apparatus 50 includes a hand held housing 52 and a docking station (not shown) for receiving the housing. A signal processor 54 (FIG. 4) disposed within the housing generates a first stimulus signal. The first stimulus signal comprises an amplitude modulated signal, which may include at least one paired tonal stimulus. A probe (or speculum) 56 extends from the housing and is shaped for easy insertion into a subject's ear. The probe is electrically coupled to the signal processor and includes a speaker 58 and a microphone 60. The speaker transmits the first stimulus signal into the ear, and the microphone receives one or more response signals from the subject's ear. The signal processor processes the response signals to provide an OAE signal, an AR signal and/or tympanometry signal.

An LCD screen 62 is located on the housing for displaying test results. Push button controls 64 are conveniently located on the housing for operation of the apparatus. The housing also includes batteries, recharging circuitry, data transfer circuitry, a pressure pump and air cavities.

In one configuration, the docking station simply includes a battery charger and a printer. Data from the housing is downloaded to memory and passed to the printer. In another configuration, the docking station includes the battery

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charger, printer, a signal processor to analyze downloaded signals, storage devices (e.g., hard disk and disk drive), serial and/or parallel ports for communication with other processors.

FIG. 4 is a block diagram of one embodiment of a portable audiometric screening apparatus configured to perform AR and OAE testing. To obtain AR measurements, the speculum 56 is inserted into the subject's ear canal without requiring a hermetic seal. An acoustic stimulus signal (e.g., a series of tones stepped from 226 Hz to 4520 Hz in 20 octave steps) are generated by the DSP chip 66 and converted to an analog signal by the D/A 68. The signal is briefly presented (i.e., on the order of milliseconds in duration) to the ear via the speaker 58. The microphone 60 transduces acoustic energy reflected off the tympanic membrane. This analog signal is filtered in a high-pass filter 70, digitized in the A/D 72, and averaged in the DSP chip 66.

The computer 74 Fourier transforms the processed signal and compares the reflected energy with the acoustic stimulus signal at each frequency. The level of sound reflected is calculated and a normalized value of the reflected signal (from 0.0 to 1.0) is plotted on the LCD screen 62 and stored in random-access-memory until the data is erased. At the completion of an AR test, the housing is placed within a well on the docking station. Electrical contacts on the base of the housing facilitate data transfer to the docking station for analysis, storage, printing, or retransmission to another computer or storage device.

To obtain OAE measurements, the speculum is inserted into the subject's ear canal. An acoustic stimulus signal is presented to the ear by the speaker. OAEs may be evoked using either transient or continuous stimulus signals. In the transient signal case, a brief click or tone burst is presented to the ear. A determination of the response signal is made by comparing the acoustic energy in the ear canal immediately following presentation of the stimulus signal with that obtained during non-stimulus periods.

In the continuous signal case, two pure tones (at frequencies f_1 and f_2) of extended duration are presented simultaneously. In a healthy ear, a response signal is re-emitted from the ear with significant energy at the cubic distortion product ($2f_1 - f_2$). These are frequently referred to as distortion product OAEs. The distortion product of the two stimulus tones is measured and compared with the energy at that frequency in the ear canal when no stimulus is presented (i.e., the continuous background "noise floor"). Any energy at the distortion product above the noise floor is due to evoked OAEs produced by the ear. The occurrence of energy in the OAE at the frequency corresponding to this cubic distortion product is a reliable test of the functional of the middle and inner ear and an extremely efficient test for use in the initial screening. Distortion product OAEs appear to be reliable predictors of hearing loss greater than 20-30 dB normal hearing level.

FIG. 5 is a block diagram of another embodiment of a portable audiometric screening apparatus configured to perform tympanometry and OAE testing. The OAE test capability is the same as described above. Tympanometry tests measure the admittance of the tympanic membrane and middle ear across a range of frequencies and over a range of pressures. To perform the test, the speculum is inserted into the ear. The speculum makes a pneumatic seal with the wall of the ear canal. An acoustic stimulus signal (e.g., user selectable combinations of pure tones at 226 Hz and 678 Hz, and 904 Hz), is transmitted into the ear by the speaker 58. The signal reflects off the tympanic membrane at the distal

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end of the ear canal and is transduced by the microphone 60. A comparison of the emitted and received signals allows a calculation of the middle ear admittance at a given pressure. The pressure in the ear canal is varied from negative to positive, relative to normal atmospheric pressure, by activating a miniature pump 76 which is located in the housing and a motor 80. A pressure transducer 78 monitors pressure in the ear. The test results are displayed on the LCD screen 62 and stored in random-access-memory until the data is erased.

The invention utilizes several acoustic stimulus signals not heretofore employed for auditory screening. For example, one or more paired tonal stimuli may be used for OAE and AEP testing. In one embodiment, a paired tonal stimulus signal includes two tones having frequencies f_1 and f_2 . To obtain OAE test results, a response signal is measured at the acoustic distortion product which corresponds to the frequency $2f_1 - f_2$. This signal has been termed the distortion product otoacoustic emission (DPOAE). For AEP tests, the response signal includes a large component corresponding to the difference in frequency between the two tones (i.e., $|f_1 - f_2|$), which is the envelope frequency of the stimulus waveform. This is termed the envelope following response (EFR).

In other embodiments, the stimulus includes multiple paired tones (e.g., f_1 and f_2 , f_3 and f_4 , f_5 and f_6). Such a signal can be used to simultaneously test at each of the frequency regions corresponding to the paired tones. For instance, if one used three paired tones of $f_1=1000$ Hz and $f_2=1040$ Hz, $f_3=3000$ Hz and $f_4=3070$ Hz, and $f_5=5000$ Hz and $f_6=5080$ Hz, hearing sensitivity can be tested simultaneously at 1000, 3000, and 5000 Hz.

A number of signal processing methods are employed in apparatuses incorporating the principles of the invention. For example, one method provides improved signal-to-noise ratio (signal-to-noise ratio) resulting in higher quality test results. For AEP and OAE tests, the evoked response (ER) is often small compared to the background noise (background noise). A high background noise level can make detection of the desired evoked response signal unreliable. A traditional solution to the signal-to-noise ratio problem has been to employ a combination of filtering, artifact rejection, and ensemble averaging. In the instant situation, the evoked response and background noise have overlapping spectra, so filtering offers only very little improvement in the signal-to-noise ratio. Artifact rejection improves the signal-to-noise by rejecting, and thereby excluding from the averaging process, sweeps which exceed some preset voltage threshold level. Sweeps which contain a large artifact (e.g., potentials resulting from brief muscle activity or loud noises such as coughing) are not included in the average if it exceeds the reject threshold level. However, it is difficult to know a priori the optimal setting for the reject level because the background activity level is not stationary. This uncertainty limits the effectiveness of the artifact rejection technique in improving the signal-to-noise ratio. Therefore, filtering and artifact rejection techniques do not significantly increase the signal-to-noise ratio of the evoked response.

The invention utilizes an ensemble averaging technique in the time domain for improving the signal-to-noise ratio. A signal $S(t)$ is recorded (from the electrodes or ear canal microphone) that includes the desired evoked response $ER(t)$ (a deterministic signal) and background noise $BN(t)$ (a non-stationary random process). The signal $S(t)$ is averaged over (m) sweeps, but since the evoked response is deterministic (i.e., it does not change in amplitude, latency, or morphology over the (m) sweeps):

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$$\overline{S(t)} = ER(t) + \overline{BN(t)} \quad (1)$$

Using a the signal-to-noise ratio estimate based on the evoked response/background noise ratio, and recognizing that the evoked response and background noise may not be totally uncorrelated, it can be shown that the magnitude of the averaged acquired signal $\overline{S(t)}$ is a function of the signal-to-noise ratio and proportional to the magnitude of the averaged background variance. Since the magnitude of $\overline{S(t)}$ is a function of the signal-to-noise ratio and background noise level, and since background noise can vary from sweep to sweep, the response signal-to-noise ratio can be maximized by expressing the variance in a single sweep or, better, in a block consisting of the average of m sweeps, relative to the estimated variance of the averaged background noise. The contribution of each block is weighted inversely to this variance ratio (i.e., individual components used in the averaging process are weighted according to their individual precision).

Using AEPs and OABs, the foregoing is applied by assuming that (as set forth in Equation (1)) the background noise is a non-stationary, Gaussian distribution with variance changing over the course of the acquisition process. Because the acquired signal is the sum of the desired evoked response (constant) and background noise (random), the precision of an individual block average is inversely proportional to the magnitude of the signal variance. Thus, the precision of each block of sweeps, along with the subsequent weighting in the averaging process, is determined as the variance of that block relative to the estimated variance of the entire average. In one implementation, if $\overline{S(t)}$ is the time waveform of the block (i.e., the average of (m) sweeps), and V is the estimated variance of the background noise after i th block, the estimate of the evoked response after the M th average will be:

$$ER_M = (S(t)/V_1 + S(t)/V_2 + \dots + S(t)/V_M) * 1/C_M \text{ where } C_M = 1/V_1 + \dots + 1/V_M \quad (2)$$

This estimate is obtained by adding together the averaged time waveforms from each block after dividing by their corresponding variances and multiplying this sum by $1/C_M$, obtained by combining all the variances, hence:

$$ER_M = 1/M (S(t)/V_1 + S(t)/V_2 + \dots + S(t)/V_M) / C_M \quad (3)$$

This may be contrasted with the "normal" ensemble average:

$$ER_M = 1/M (S(t) + S(t) + \dots + S(t)) \quad (4)$$

The difference is that in "normal" averaging each block is given equal weight (i.e., independent of the level of background noise level in that block), whereas in the current estimate the i th block is weighed inversely proportional to the level of the background noise in that block. When the background noise is constant across blocks, then the two estimates are identical. When the background noise varies, however, the current technique (by minimizing the contribution of noise-contaminated sweeps) yields a significantly improved estimate of the evoked response by increasing the signal-to-noise ratio.

As noted previously, the evoked response is typically buried in the background noise. Many techniques for the

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detection of AEPs utilize time-domain analysis of the transient evoked ABR waveform. Although detection of OABs is typically performed in the frequency domain, only magnitude information of identified Fourier components is utilized. In the following technique, the relation between real and imaginary parts of Fourier components is fully utilized.

In steady-state AEP or OAB testing, each block of sweeps yields an evoked response to a periodic stimulus signal. Since the evoked response is also periodic, it may be described by its Fourier components. In auditory tests measuring AEPs in response to amplitude modulated stimuli, the response at the frequency corresponding to the stimulus envelope (i.e., the EFR) is determined. Similarly, in DPOAE tests the response at the distortion component corresponding to $2f_1 - f_2$ is measured. At these frequencies, the Fourier component is a complex number z which can be expressed in a Cartesian representation $z = x + jy$. Further, the values x and y represent the cosine and sine components of the evoked response. This formulation makes explicit the notion that z is a vector in the x, y plane. With multiple estimates of z , a cluster of vectors is built up in the complex plane. The pooled estimate of the evoked response lies in the center of the cluster, and the reliability of the pooled estimate is indicated by the degree of scatter. Estimation of the amount of scatter within the cluster should provide an index of the extent that the true evoked response may deviate from the mean of the observed response.

In audiometric tests, responses to a stimulus are collected in M blocks, with each block consisting of the average of (m) individual sweeps. Thus, a set of M estimates of the Fourier component z corresponding to the frequency of the stimulus waveform envelope is made available. To determine whether evoked response is present, it must be determined whether these estimates are consistent within an "a priori" value. The M estimates of this Fourier component can be denoted by z_1, z_2, \dots, z_{M2} their empirical mean value by $z_{est} = (Ez)/M$, and an "a priori" hypothetical value by δ . Each of the quantities z_j , z_{est} and δ are complex numbers, decomposable into real and imaginary parts: $z_j = x_j + jy_j$; $z_{est} = x_{est} + jy_{est}$, and $\delta = e + j\eta$. From the scatter of individually determined components z_j about their mean, with each of the deviations $x_j - x_{est}$ and $y_j - y_{est}$, providing one estimate, an estimate of the individual population variance is made:

$$V_{ind} = (1/2(M-1))[(x_j - x_{est})^2 + (y_j - y_{est})^2] = (1/2(M-1))E(z_j - z_{est})^2 \quad (5)$$

which is independent of the assumed population mean δ .

A second estimate, referred to as the group variance, is dependent on δ . Because the real and imaginary parts of z_{est} are independently distributed and unconstrained by V_{ind} , a second group variance estimate is as follows:

$$V_{group} = M/2 [(x_{est} - e)^2 + (y_{est} - \eta)^2] = (1/2(M-1))E(z_{est} - e)^2 \quad (6)$$

The estimate of the Fourier component for each block of (m) samples, z_j , are subsamples of a population whose mean is δ , and the quantities V_{ind} and V_{group} are estimates of the overall variance derived from independent quantities. Therefore, the ratio V_{group}/V_{ind} is distributed according to the F distribution. Based on this variance ratio, a statistical approach is utilized wherein:

$$R = (1/M) (V_{group}/V_{ind}) - (M-1) [(z_{est} - e)^2 E(z_j - e)^2] \quad (7)$$

Therefore, for M independent estimates of Fourier components z_j , drawn from a sample of assumed mean δ , $M \cdot R$ is

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distributed according to $F_{(2,2N-2)}$.

This statistic, unlike other methods, fully utilizes the independence of the real and imaginary parts of the Fourier component of interest and is used for detecting the presence of a response by determining if the observed set of Fourier components z_n at the frequency corresponding to the stimulus envelope or cubic distortion product, is consistent with random fluctuations alone (i.e., no response signal), or whether the set of observations implies, to within a given confidence level, that a response component is present.

In conducting audiometric studies using AEPs or OAEs, a standard procedure has been to specify that a fixed number of sweeps be acquired. However, as noted above, in situations in which the subject is quiet, with relatively low background noise, or when the stimulus is considerably above threshold, a large evoked response will be recorded with a correspondingly high signal-to-noise ratio. Thus, only relatively few sweeps are required to obtain an acceptable response. Alternatively, in situations where the subject is noisy (either episodic or during an entire test session), or where the stimulus is close to threshold, then the response is smaller or buried in larger noise, with a resultant lowered signal-to-noise ratio. In these conditions, a large number of sweeps may be required. If the artifact rejection threshold is set sufficiently low to exclude such episodic noise, or if the subject displays a sustained period of relatively high noise level, then no sweeps need be added to the accumulating buffer for averaging. By lowering the reject threshold, fewer noise-contaminated sweeps are included in the average (yielding in a higher signal-to-noise ratio), but this is at a cost of greatly prolonging the test time required to achieve a preset number of sweeps. The specification of a fixed number of sweeps is clearly an inefficient approach. In some instances, the number may be excessive (needlessly prolonging the test) or insufficient (thereby yielding an unacceptably low signal-to-noise ratio). It is quite difficult to predict "a priori" the number of sweeps required to achieve a given signal-to-noise ratio—just as it is quite difficult to preset an optional artifact rejection level. However, a "a priori" the number of sweeps required to achieve a given signal-to-noise ratio just as it is quite difficult to preset an optional artifact rejection level. However, a means to estimate the quality of the obtained evoked response on an ongoing basis is available from the variances already calculated. The ratio of the variance of the averaged response block to the estimated variance of the ongoing background noise can be treated as an F-distribution:

$$F_p = \text{VAR}(\text{ER}(t)) / \text{VAR}(N(t)) \quad (8)$$

In automating the test, stimulus presentation and response acquisition continues until a prespecified criterion value for acceptance is met.

The signal processing described above, although widely applicable for use with a variety of stimulus signal types, is particularly useful in facilitating acquisition and detection of responses using DPOAE and EFR tests described above. The hardware and software of the present system makes possible the acquisition and automated detection of both DPOAEs and AEPs simultaneously.

EQUIVALENTS

While the invention has been particularly shown and described with reference to specific preferred embodiments, it should be understood by those skilled in the art that

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various changes in form and detail may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

I claim:

1. An audiometric apparatus comprising:

a signal processor for generating a first stimulus signal; a probe electrically coupled to the signal processor and insertible in a subject's ear, the probe including (i) a transmitter for transmitting the first stimulus signal into the subject's ear and (ii) a receiver for receiving a first response signal from the subject's ear;

an electrode, electrically coupled to the signal processor and attachable to the subject's scalp, for sensing a second response signal from the subject's scalp; and

the signal processor processing the first response signal to provide an evoked otoacoustic emission signal and processing the second response signal to provide an auditory evoked potential signal.

2. The apparatus of claim 1 wherein the first stimulus signal comprises an amplitude modulated signal.

3. The apparatus of claim 1 wherein the first stimulus signal comprises at least one paired tonal stimuli.

4. The apparatus of claim 1 wherein the signal processor processes the first and second response signals in parallel.

5. The apparatus of claim 4 wherein the signal processor processes the first and second response signals simultaneously.

6. The apparatus of claim 1 wherein the signal processor generates a second stimulus signal, the transmitter transmits the second stimulus signal into the subject's ear, the receiver receives a third response signal from the subject's ear, and the signal processor processes the third response signal to provide an acoustic reflectivity signal.

7. The apparatus of claim 1 further comprising a plurality of electrodes, electrically coupled to the signal processor and connectable to the subject's scalp, for sensing a second response signal from the subject's scalp.

8. The apparatus of claim 1 further comprising:

a digital signal processing element;

a memory electrically coupled to the digital signal processing element;

a digital-to-analog converter electrically coupled to the digital signal processing element for converting the first stimulus signal from a digital format into an analog format;

an attenuator electrically coupled to the digital-to-analog converter for regulating the first stimulus signal;

a filter electrically coupled to the receiver and the electrode for filtering the first and second response signals;

an analog-to-digital converter electrically coupled to the filter for converting the first and second response signals from an analog format into a digital format for the digital signal processing element.

9. The apparatus of claim 8 further comprising:

a first amplifier electrically coupled to the probe for providing amplified first response signals to the filter; and

a second amplifier electrically coupled to the electrode for providing amplified second response signals to the filter.

10. The apparatus of claim 1 further comprising:

a control processor for requesting an evoked otoacoustic emission signal and an auditory evoked potential signal;

a display electrically coupled to the control processor for displaying one or more characteristics of the evoked

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12 IN THE UNITED STATES DISTRICT COURT
13 FOR THE NORTHERN DISTRICT OF CALIFORNIA

15 NATUS MEDICAL INCORPORATED, a
16 Delaware corporation

17 Plaintiff,

18 v.

19 INTELLIGENT HEARING SYSTEMS, a Florida
20 corporation,

21 Defendant.

FILED

2010 FEB 19 A 9:32

RICHARD W. WIEKING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

(19)

8-155

HRL

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707

Civil Action No.

COMPLAINT FOR PATENT
INFRINGEMENT OF U.S.
PATENT NOS. 5,601,091;
5,916,174; and 6,832,663;

DEMAND FOR JURY TRIAL

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otoacoustic emission signal and the auditory evoked potential signal; and
 an input device electrically coupled to the control processor to enable a user to request the evoked otoacoustic emission signal and the auditory evoked potential signal.

11. An auditory screening method comprising:
 attaching an electrode to a subject's scalp;
 inserting a probe, including a transmitter and a receiver, in a subject's ear;
 transmitting a first stimulus signal from the transmitter into the subject's ear;
 receiving a first response signal from the subject's ear via the receiver;
 sensing a second response signal from the subject's scalp via the electrode; and
 processing the first response signal to provide an evoked otoacoustic emission signal and the second response signal to provide an auditory evoked potential signal.

12. The method of claim 11 wherein the first stimulus signal comprises an amplitude modulated signal.

13. The method of claim 11 wherein the first stimulus signal comprises at least one paired tonal stimuli.

14. The method of claim 11 further comprising processing the first and second response signals in parallel.

15. The method of claim 11 further comprising processing the first and second response signals simultaneously.

16. The method of claim 11 further comprising displaying one or more characteristics of the evoked otoacoustic emission signal and the auditory evoked potential signal.

17. The method of claim 9 further comprising:
 generating a second stimulus signal;
 transmitting the second stimulus signal into the subject's ear;
 receiving a third response signal from the subject's ear; and
 processing the third response signal to provide an acoustic reflectivity signal.

18. An auditory screening method comprising:
 attaching an electrode to a subject's scalp;
 inserting a probe in a subject's ear;
 generating a first stimulus signal comprising a plurality of paired tonal stimuli;
 transmitting the first stimulus signal from the probe into the subject's ear;
 receiving a first response signal from the subject's ear via the probe;
 sensing a second response signal from the subject's scalp via the electrode; and
 processing the first response signal to provide an evoked otoacoustic emission signal and processing the second response signal to provide an auditory evoked potential signal.

19. The method of claim 18 further comprising processing the first and second response signals in parallel.

20. The method of claim 14 further comprising:
 generating a second stimulus signal;
 transmitting the second stimulus signal into the subject's ear;
 receiving a third response signal from the subject's ear; and
 processing the third response signal to provide an acoustic reflectivity signal.

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21. An auditory screening method comprising:
 attaching an electrode to a subject's scalp;
 inserting a probe in a subject's ear;
 transmitting a stimulus signal into the subject's ear;
 receiving a response signal from the subject's ear via the probe; and
 averaging the response signal over a plurality of intervals to produce a plurality of subaverages;
 inversely weighting each subaverage; and
 combining the inversely weighted subaverages to produce an auditory indication signal.

22. The method of claim 21 wherein the auditory indication signal is an evoked otoacoustic emission signal and or an auditory evoked potential signal.

23. The method of claim 21 wherein the first stimulus signal comprises an amplitude modulated signal.

24. The method of claim 21 further comprising inversely weighting each subaverage based the variance and content of the response signal.

25. The method of claim 21 wherein the combining step comprises averaging the inversely weighted subaverages to produce an auditory indication signal.

26. The method of claim 25 wherein the combining step comprises:
 performing a Fourier transform for each subaverage;
 determining real and imaginary components of the Fourier transform at specified frequencies;
 independently estimating variance of each component; and
 determining the probability of an auditory indication signal using an F statistic.

27. An audiometric apparatus comprising:
 a hand-held housing;
 a signal processor, disposed in the housing, for generating a first and second stimulus signals;
 a probe extending from the housing and insertible in a subject's ear, the probe including (i) a transmitter for transmitting the first and second stimulus signals into the subject's ear and (ii) a receiver for receiving first and second response signals from the subject's ear; and
 the signal processor processing the first response signal to provide an evoked otoacoustic emission signal and processing the second response signal to provide an auditory indication signal.

28. The apparatus of claim 27 wherein the auditory indication signal is a tympanometry signal or an acoustic reflectivity signal.

29. The apparatus of claim 27 wherein the first stimulus signal comprises an amplitude modulated signal.

30. The apparatus of claim 27 wherein first stimulus signal comprises at least one paired tonal stimuli.

31. The apparatus of claim 27 wherein the signal processor processes the first and second response signals in parallel.

32. The apparatus of claim 27 further comprising:
 a digital signal processing element;
 a memory electrically coupled to the digital signal processing element;
 a digital-to-analog converter electrically coupled to the digital signal processing element for converting the first stimulus signal from a digital format into an analog format;
 an attenuator electrically coupled to the digital-to-analog converter for regulating the first stimulus signal;

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an amplifier electrically coupled to the receiver for providing amplified first response signals;
a filter electrically coupled to the amplifier for filtering the first and second response signals;

an analog-to-digital converter electrically coupled to the filter for converting the first and second response signals from an analog format into a digital format for the digital signal processing element.

33. The apparatus of claim 27 further comprising:

a control processor for requesting an evoked otoacoustic emission signal and an auditory evoked potential signal;

a display electrically coupled to the control processor for displaying one or more characteristics of the evoked otoacoustic emission signal and the auditory evoked potential signal; and

an input device electrically coupled to the control processor to enable a user to request the evoked otoacoustic emission signal and the auditory evoked potential signal.

34. The apparatus of claim 27 further comprising a docking station for receiving the housing, the docking station including a battery charger for recharging the signal

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processor and a printer for printing one or more characteristics of evoked otoacoustic emission signal and the auditory evoked potential signal.

35. An auditory screening method comprising:

inserting a probe, including a transmitter and receiver, in a subject's ear;

transmitting first and second stimulus signals from the transmitter into the subject's ear;

receiving first and second response signals from the subject's ear via the receiver; and

processing the first response signal to provide an evoked otoacoustic emission signal and processing the second response signal to provide an auditory indication signal.

36. The method of claim 35 wherein the auditory indication signal is a tympanometry signal or an acoustic reflectivity signal.

37. The method of claim 35 further comprising displaying the evoked otoacoustic emission signal and the auditory evoked potential signal.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,601,091
DATED : February 11, 1997
INVENTOR(S) : William Ford Dolphin

Page 1 of 1

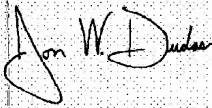
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page, Item [54] and Column 1, lines 1-2.

Title, should read as follows: -- AUDIOMETRIC APPARATUS AND
ASSOCIATED SCREENING METHOD. --.

Signed and Sealed this

Ninth Day of November, 2004

A handwritten signature in black ink, appearing to read "Jon W. Dudas", is written over a rectangular area of fine dots.

JON W. DUDAS

Director of the United States Patent and Trademark Office

EXHIBIT B



US005916174A

United States Patent [19]**Dolphin**[11] **Patent Number:** **5,916,174**[45] **Date of Patent:** ***Jun. 29, 1999****[54] AUDIOMETRIC APPARATUS AND ASSOCIATED SCREENING METHOD****[75] Inventor:** William F. Dolphin, Weston, Mass.**[73] Assignee:** Sonamed Corporation, Weston, Mass.**[*] Notice:** This patent is subject to a terminal disclaimer.**[21] Appl. No.:** 08/797,039**[22] Filed:** Feb. 10, 1997**Related U.S. Application Data****[63]** Continuation of application No. 08/509,836, Aug. 1, 1995, Pat. No. 5,601,091.**[51] Int. Cl.⁶** **A61B 5/00****[52] U.S. Cl.** **600/559; 600/378; 73/585****[58] Field of Search** **128/746, 731; 73/585; 600/379, 301, 378, 544, 555, 559****[56] References Cited****U.S. PATENT DOCUMENTS**

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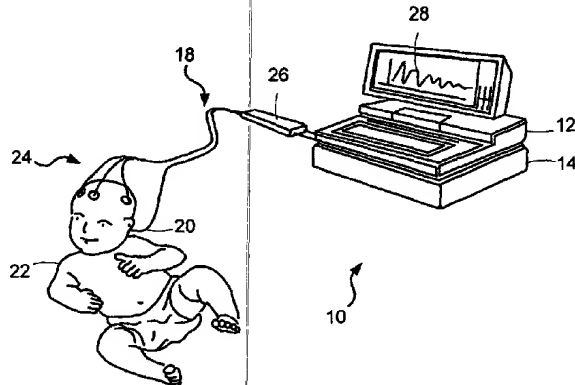
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OTHER PUBLICATIONSDobie et al.; "Objective response detection in the frequency domain"; *Electrophysiology*, 88 (1993) pp. 516-524.Susan C. Gorin; "Special features of immittance equipment—Then and now"; *Hearing Instruments*, 42 (8) (1991) p. 1517.Moore et al.; "A Microcomputer-Based System for Auditory Evoked Potentials"; *Scand Audiol*, 18 (1989) pp. 135-141.*Primary Examiner*—Mickey Yu*Assistant Examiner*—Dinh X. Nguyen*Attorney, Agent, or Firm*—Testa, Hurwitz & Thibault LLP**[57]****ABSTRACT**

An audiometric screening apparatus and associated method provides fast, low-cost, noninvasive screening of a subject's hearing. The apparatus includes a signal processor for generating a stimulus signal and a probe electrically coupled to the signal processor and insertible in a subject's ear. The probe includes a transmitter to transmit the stimulus signal into the ear and a receiver for receiving a first response signal from the subject's ear. An electrode, electrically coupled to the signal processor, is attached to the subject's scalp for sensing a second response signal. The signal processor processes the first response signal to provide an evoked otoacoustic emission signal and processes the second response signal to provide an auditory evoked potential signal.

29 Claims, 3 Drawing Sheets

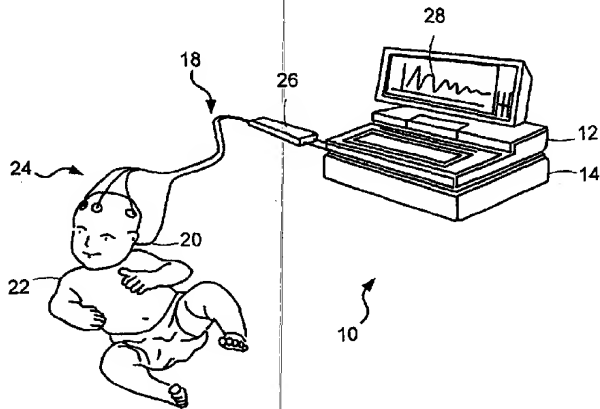


FIG. 1

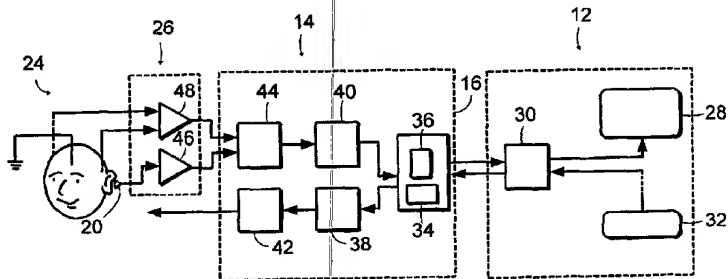


FIG. 2

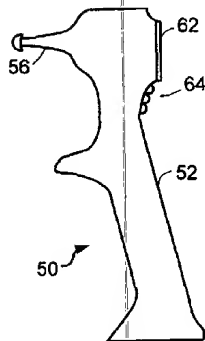


FIG. 3

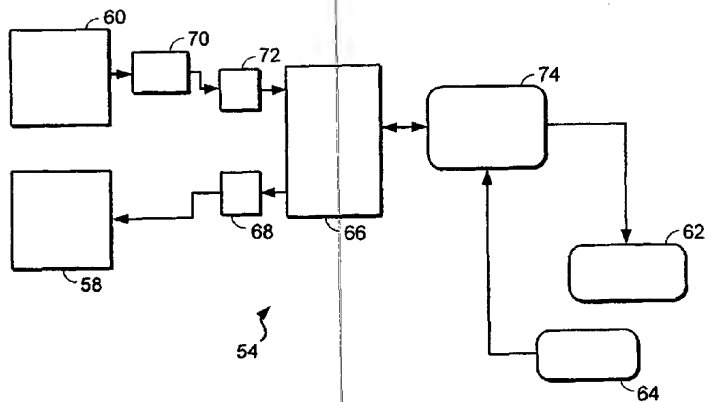


FIG. 4

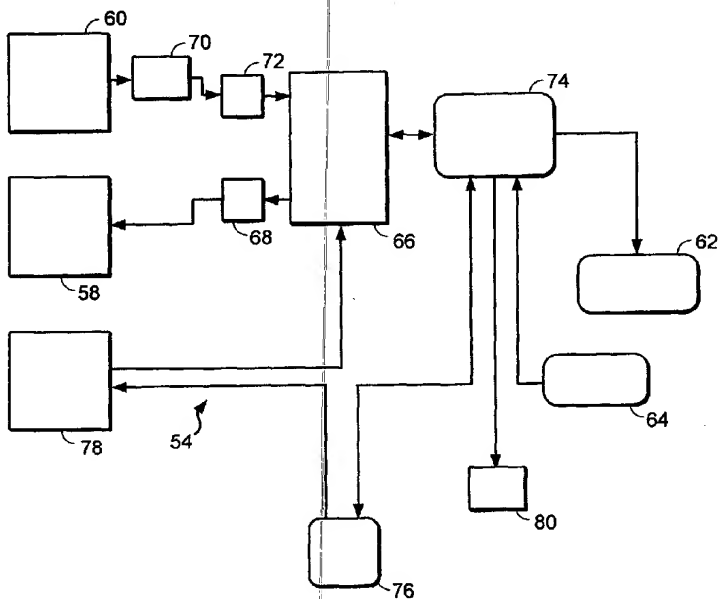


FIG. 5

1 **AUDIOMETRIC APPARATUS AND ASSOCIATED SCREENING METHOD**

This is a continuation Ser. No. 08/509,836 filed on Aug. 1, 1995, now U.S. Pat. No. 5,601,091.

BACKGROUND

The present invention relates generally to the field of audiometric apparatuses and associated screening methods. In particular, the invention relates to audiometric apparatuses and auditory screening methods for providing rapid, low-cost, comprehensive, non-invasive screening of a subject's hearing.

Language acquisition in infants requires a critical period of hearing capacity which spans the frequency range of human speech. The critical period extends from birth to about two to three years of age, when infants typically begin to talk with some level of proficiency.

Approximately three to five percent of newborn infants suffer from some degree of hearing impairment. These impairments can be devastating to the social, emotional and intellectual development of the affected infants. Early identification of hearing impairments in infants allows for early intervention to minimize significant speech and language deficiencies. Infants are usually unable or unwilling to participate in known behavioral auditory examinations. Moreover, delaying auditory screening until infants can verbally respond is often too late for hearing impaired infants and results in long term problems.

Federal, state and private agencies have attempted to implement universal auditory screening of infants for over twenty years. A major impediment to the implementation of universal auditory screening of infants has been the cost and complexity associated with the tests. Current infant screening tests are time consuming and require expensive devices and trained specialists to conduct the tests and interpret results. As such, universal auditory screening of infants is presently economically infeasible.

Various entities have developed audiometric devices which may be useable for screening an infant's hearing. These existing devices generally fall into one of two categories. Devices in the first category are configured to elicit auditory evoked potentials (AEPs), which are electrical responses of cells within the auditory pathway of the brain to an acoustic stimulus. Such devices typically utilize the non-invasive auditory brainstem response (ABR) test for auditory screening of infants. An earphone provides an acoustic stimulus, specifically a brief click or toneburst, to the subject's ear. Electrodes attached to the subject's scalp receive auditory evoked potentials from the scalp, which are recorded as an electroencephalogram waveform. Analysis of these brainwave patterns are used to determine if the auditory system is functioning normally.

Devices in the second category utilize the evoked otoacoustic emission (OAE) test for auditory screening. An earphone provides a brief acoustic stimulus to the subject's ear. A microphone disposed in the subject's ear adjacent the earphone receives an OAE from the ear, which is recorded as an acoustic signal. Analysis of the OAE waveform provides an indication of the functional integrity of the middle and inner ear, which together comprise the auditory periphery.

A number of limitations exist with respect to existing audiometric screening devices. One limitation is that some existing devices are complicated and require extensive training to operate. Another limitation is that other devices only

provide a pass/fail indication and lack a visual display. Yet another limitation is that two separate devices are required to perform both the ABR or OAE tests. An operator typically makes a subjective determination of the acceptability of the ABR or OAE test results based on a visual examination of the response waveforms. Because existing audiometric devices do not allow for rapid, low-cost, non-invasive, comprehensive screening of infants, such devices do not adequately address the need for universal auditory infant screening.

2 **SUMMARY OF THE INVENTION**

The present invention contemplates audiometric screening apparatuses and associated methods for providing rapid, low-cost, comprehensive, non-invasive screening of a subject's hearing. An advantage of performing auditory screening using apparatuses incorporating the principles of the invention is that a behavioral response from the subject is not required. Thus, such apparatuses can be used to screen subjects who are unable to respond (e.g., infants) or unwilling or difficult to test (e.g., unconscious or mentally handicapped persons). Another advantage is that the invention is particularly useful in the area of auditory screening of infants. Except for initial infant preparation, the apparatus provides a fully automated screening procedure which includes stimulus presentation, response signal acquisition, signal analysis and interpretation of results. Nurses, technicians or hospital volunteers only require minimal training to perform auditory screening of infants. Thus, the cost of administering such auditory screening tests is reduced, encouraging universal screening of newborn infants.

The invention features an audiometric apparatus for screening a subject's hearing. The apparatus includes a signal processor for generating a first stimulus signal. A probe is electrically coupled to the signal processor and insertible in a subject's ear. The first stimulus signal comprises an amplitude modulated modulated acoustic signal which may include at least one paired tonal stimulus or at least one triple tonal stimulus. The probe includes a transmitter to transmit the first stimulus signal into the ear and a receiver for receiving a first response signal from the subject's ear. At least one electrode, electrically coupled to the signal processor, is attached to the subject's scalp for sensing a second response signal. The signal processor processes the first response signal to provide an OAE signal and processes the second response signal to provide an AEP signal. The signal processor processes the first and second signals in parallel. Moreover, the signal processor may process signals simultaneously to provide simultaneous OAE and AEP signals.

An input device is electrically coupled to a control processor to enable a user to request the signal processor to perform OAE and AEP tests. A display is electrically coupled to the control processor for displaying one or more characteristics of the OAE and AEP signals.

The apparatus may further include the capability to perform acoustic reflectivity (AR) tests. Such tests measure the degree to which sound across a range of frequencies is reflected off of the tympanum. The signal processor generates a second stimulus signal which is transmitted into the subject's ear by the transmitter. The receiver receives a third response signal from the subject's ear, and the signal processor processes the third response signal to provide an AR signal. The AR signal indicates the presence of fluid in the middle ear cavity and other pathologies.

The invention also features a portable audiometric apparatus for screening a subject's hearing. The portable appa-

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ratus includes a hand held housing and a docking station for receiving the housing. The docking station includes a battery charger for recharging the signal processor and a printer. A signal processor disposed within the housing generates a first stimulus signal. The first stimulus signal comprises an amplitude modulated signal, which may include at least one paired tonal stimulus or at least one triple tonal stimulus. A probe, electrically coupled to the signal processor, extends from the housing and is insertible into a subject's ear. The probe includes a transmitter to transmit the first stimulus signal into the ear and a receiver for receiving a first and second response signals from the subject's ear. The signal processor processes the first response signal to provide an OAE signal and processes the second response signal to provide an auditory indication signal. The auditory indication signal may be a tympanometry signal or an AR signal.

An input device electrically coupled to a control processor to enable a user to request the signal processor to perform OAE and auditory indication tests. A display is electrically coupled to the control processor for displaying one or more characteristics of the OAE and auditory indication signals.

The invention also features an auditory screening method for providing comprehensive screening of a subject's hearing. An electrode is attached to a subject's scalp. A probe, including a transmitter and a receiver, is inserted in the subject's ear. A stimulus signal is transmitted into the subject's ear. The stimulus signal comprises an amplitude modulated signal, which may include at least one paired tonal stimulus or at least one triple tonal stimulus. A response signal is received from the subject's ear via the probe. The response signal is averaged over a plurality of intervals to produce a plurality of subaverages. The subaverages are weighted based on a derived estimate of response content and combined to produce an auditory indication signal.

More specifically, the subaverages are inversely weighted based on the variance and content of the response signal. Further, the inversely weighted subaverages are combined according to the following steps: (i) performing a Fourier transform for each subaverage, (ii) determining real and imaginary components of the Fourier transform at specified frequencies, (iii) independently estimating variance of each component, and (iv) determining the probability of an auditory indication signal using an F statistic.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features of the invention are more fully described below in the detailed description and accompanying drawings of which the figures illustrate audiometric apparatuses and methods.

FIG. 1 is an illustration of an audiometric screening apparatus incorporating the principles of the invention.

FIG. 2 is a block diagram of the audiometric screening apparatus shown in FIG. 1.

FIG. 3 is an illustration of a portable audiometric screening apparatus illustrating the principles of the invention.

FIG. 4 is a block diagram of one embodiment of the portable audiometric screening apparatus shown in FIG. 3.

FIG. 5 is a block diagram of another embodiment of the portable audiometric screening apparatus shown in FIG. 3.

DETAILED DESCRIPTION OF THE INVENTION

The invention contemplates audiometric screening apparatuses for providing rapid, low-cost, comprehensive, non-

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invasive screening of a subject's hearing. Such apparatuses provide a fully automated screening procedure including stimulus presentation, response signal acquisition, signal analysis and interpretation of results. Thus, minimally trained personnel can perform auditory screening tests. Moreover, since such apparatuses do not require a behavioral response from the subject, they are particularly useful for screening infants, unconscious persons or mentally handicapped persons.

In one embodiment, an audiometric screening apparatus incorporating the principles of the invention is capable of performing OAE testing, ABR testing and AR testing. OAE tests take advantage of nonlinearities in the healthy auditory system in obtaining OAE signals. The procedure requires that an acoustic stimulus signal be presented to the subject's ear. The acoustic energy is conducted, via structures of the middle ear, to the fluid filled cochlea. Pressure waves propagating within the fluid result in displacements of the basilar membrane. Such displacements cause excitation of inner and outer hair cells. It is believed that, due to active processes primarily associated with length changes in outer hair cells, energy is retransmitted in a retrograde manner out of the cochlea and conducted through the middle ear to the eardrum. This retransmitted energy causes movement of the eardrum which acts as a speaker, producing acoustic energy detectable in the ear canal. Due to nonlinearities of the ear, this retransmitted sound, which is measured as an OAE, occurs at frequencies other than those present in the original stimulus.

The ABR test is a noninvasive procedure in which an acoustic stimulus signal, such as a brief click or toneburst, is presented to the subject's ear. Electrical potentials are recorded from the scalp using electrodes. In a normally functioning auditory system, a suprathreshold sound stimulates cells within the auditory pathway of the brain (primarily neurons comprising the auditory nerve and brainstem structures). This excitation spreads from the peripheral to more central structures resulting in the discharge of large numbers of neurons within the pathway. The neural activity is time-locked to the acoustic stimulus signal resulting in the synchronized discharge of large neuronal assemblies. As excitation moves through the auditory system, a sequential pattern of electrical potentials are measured from the scalp which appear as a highly stereotypical series of waves on an electroencephalogram. Analysis of these acoustically evoked brainwave patterns can be used to determine if the auditory system is functioning normally.

AR tests measure the degree to which sound across a range of frequencies is reflected off of the tympanum. An stimulus signal is transmitted into the subject's ear, and an AR response signal is received therefrom. The AR signal provides an indication of the presence of fluid in the middle ear cavity.

FIG. 1 illustrates an audiometric screening apparatus incorporating the principles of the invention. The apparatus 10 is controlled by a laptop computer 12. The computer is electrically connected to a docking station 14. A signal processor 16 (FIG. 2) disposed in the docking station generates acoustic stimulus signals in response to computer commands. A probe 18 includes an earphone 20 for presenting acoustic stimulus signals generated by the signal processor to the (infant) subject 22. The earphone also receives an OAE response signal from the subject's ear. Electrodes 24 attached to the subject's scalp sensing an ABR response signal. The response signals are amplified in a bioamplifier unit 26 and provided to the signal processor for processing and analysis. One or more characteristics of the processed

1 Plaintiffs Natus Medical Incorporated, a Delaware corporation ("Natus")
2 hereby complains of Defendant Intelligent Hearing Systems ("IHS"), a Florida corporation
3 and alleges as follows:

4 **JURISDICTION AND VENUE**

5 1. This Complaint states causes of action for patent infringement arising under
6 the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and, more particularly, 35
7 U.S.C. §§ 271 and 281. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331
8 and 1338(a).

9 2. Upon information and belief, IHS conducts business throughout the United
10 States, including in this judicial district, and has committed the acts complained of in this
11 judicial district and elsewhere.

12 3. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and
13 1400(b).

14 **PARTIES**

15 4. Natus is a Delaware corporation having its principal place of business at 1501
16 Industrial Road, San Carlos, CA.

17 5. Upon information and belief, IHS is a Florida corporation having its principal
18 place of business at 6860 Southwest 81st Street, Miami, FL.

19 **ALLEGATIONS FOR ALL CLAIMS OF RELIEF**

20 6. On February 11, 1997, the United States Patent and Trademark Office duly
21 and lawfully issued U.S. Patent No. 5,601,091 ("the '091 patent"), titled "Audiometric
22 Apparatus and Associated Screening Method." Natus owns the '091 patent by assignment. A
23 copy of the '091 patent is attached hereto as Exhibit A.

24 7. On June 29, 1999, the United States Patent and Trademark Office duly and
25 lawfully issued U.S. Patent No. 5,916,174 ("the '174 patent"), titled "Audiometric Apparatus
26 and Association Screening Method." Natus owns the '174 patent by assignment. A copy of
27 the '174 patent is attached hereto as Exhibit B.

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OAE and AEP signals are displayed on the computer monitor 28 along with other pertinent information and other middle and inner ear pathologies.

Using a plurality of signal processing algorithms, the processed response signals are analyzed to detect the presence of a response, and, alternatively or additionally, compared with age weighted population normal signals stored in memory. If the processed response signals compare favorably with the population normal signals, the subject "passes" the screening test. If responses deviate from population normal signals by greater than a specified acceptance tolerance, the subject is "referred" for further diagnostic examinations.

The apparatus 10 may further include the capability to perform acoustic reflectivity (AR) tests. Such tests measure the degree to which sound across a range of frequencies is reflected off of the tympanum. The signal processor generates a stimulus signal which is transmitted into the subject's ear by the earphone. A third response signal from the subject's ear is received by the earphone and passed to the signal processor for processing. A processed AR signal, providing an indication the presence of fluid in the middle ear cavity, is displayed on the monitor.

FIG. 2 is a block diagram of the audiometric screening apparatus shown in FIG. 1. The apparatus includes three main components: the computer 12, the docking station 14 and the bioamplifier unit 26. The computer includes the monitor 28, a control processor 30 and a keyboard 32. The docking station includes a signal processor 16 (which includes one or more digital signal processing (DSP) chip 34 and memory 36), analog-to-digital (A/D) converters 38, digital-to-analog (D/A) converters 40, attenuators 42 and filters 44. The bioamplifier unit includes the probe 18 and response signal amplifiers 46 and 48.

The apparatus is controlled by the computer which communicates with the docking station via an ISA bus. A safe connection between the standard 60Hz wall plug and the docking station is provided by a toroidal isolation transformer (not shown) meeting all UL 544 requirements. In one configuration, the computer includes the following components: an 86-family IBM-compatible processor, 4MB of memory, a 80 MB hard-drive, and VGA-compatible graphics card and monitor. An operator specifies the test procedure including test type(s), stimulus signal frequencies, intensities, etc. using the keyboard, a mouse or voice input.

The DSP chip 34 digital generates the acoustic stimulus signals used in the auditory tests. In one configuration, the DSP chip is a 32-bit floating point processor and the associated memory 36 includes 4MB of DRAM. The digital signal generated by the DSP is converted to analog voltage using the (16 bit) D/A converter 38 with two multiplexed channels operating at 500 kHz in single channel mode. The analog signal is passed to the programmable attenuators 42 which have attenuation range of 0.0 to 99.9 dB. The attenuated analog signal is passed to the earphone 20. The analog signal is transmitted by speakers within earphone to stimulate the auditory system of the subject. In the OAE test, OAE responses to the stimulus signals are detected using a microphone disposed in the earphone. More specifically, the OAEs are evoked using two long duration, simultaneously presented pure tones. The tones are presented at frequencies f_1 and f_2 . In a healthy ear, an analog response signal is remitted from the ear with significant energy at frequency corresponding to the cubic distortion product ($2f_1 - f_2$). In the AEP test, analog response signals are acquired from the scalp are detected using the electrodes 24.

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In either case, the response signals from the subject are directed to the bioamplifier unit 26 which complies to UL544 and IEC601 standards. The bioamplifier unit is custom designed capable of parallel and simultaneous presentation of two acoustic stimulus signals, acquisition of OAEs from within the ear canal and AEPs from the scalp. The bioamplifier unit is fully programmable, but also has manual controls. Also, the bioamplifier unit includes an impedance meter for testing the electrode impedance used in acquisition of AEPs.

The response signals are amplified in the bioamplifier unit using separate amplifiers 46 and 48 and directed to the docking station. Within the docking station, the signals are passed through anti-aliasing filters 44 and digitized using a 16-bit A/D 40. The digitized signals are written to memory buffers in the signal processor 16, averaged by the DSP chip 34 and uploaded to the computer 12 for storage on a hard drive and display on the monitor 28.

In another embodiment, a portable hand-held audiometric screening apparatus incorporating the principles of the invention is capable of performing OAE testing, AR testing and tympanometry testing. The principles of OAE and AR testing are described above. Tympanometry tests are used to measure the acoustic admittance (or "absorption") of the tympanic membrane and middle ear system at select frequencies over a range of atmospheric pressures. Tympanometry devices typically serve as diagnostic instruments for detecting the presence of fluid in the middle ear cavity.

One primary function of the portable hand-held audiometric screening apparatus is to determine the status of the middle ear, particularly otitis media and collection of fluid in middle ear (middle ear effusion). Such conditions can seriously affect the results of audiometric tests. Middle ear status can be determined by AR otoscopy or tympanometry. It is recommended that an AR or tympanometry test be conducted immediately prior to OAE or ABR testing.

Another primary function of the portable audiometric screening apparatus is to perform OAE tests to determine whether the auditory periphery is functioning normally. In auditory screening of infants, the OAE test may be used with the objective of eliminating all babies with normally functioning auditory peripheries. Those babies that fail the initial test may be rescreened using other diagnostic tests.

FIG. 3 illustrates a portable audiometric apparatus for screening a subject's hearing. The apparatus 50 includes a hand held housing 52 and a docking station (not shown) for receiving the housing. A signal processor 54 (FIG. 4) disposed within the housing generates a first stimulus signal. The first stimulus signal comprises an amplitude modulated signal, which may include at least one paired tonal stimulus. A probe (or speculum) 56 extends from the housing and is shaped for easy insertion into a subject's ear. The probe is electrically coupled to the signal processor and includes a speaker 58 and a microphone 60. The speaker transmits the first stimulus signal into the ear, and the microphone receives one or more response signals from the subject's ear. The signal processor processes the response signals to provide an OAE signal, an AR signal and/or tympanometry signal.

An LCD screen 62 is located on the housing for displaying test results. Push button controls 64 are conveniently located on the housing for operation of the apparatus. The housing also includes batteries, recharging circuitry, data transfer circuitry, a pressure pump and air cavities.

In one configuration, the docking station simply includes a battery charger and a printer. Data from the housing is

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downloaded to memory and passed to the printer. In another configuration, the docking station includes the battery charger, printer, a signal processor to analyze downloaded signals, storage devices (e.g., hard disk and disk drive), serial and/or parallel ports for communication with other processors.

FIG. 4 is a block diagram of one embodiment of a portable audiometric screening apparatus configured to perform AR and OAE testing. To obtain AR measurements, the speculum 56 is inserted into the subject's ear canal without requiring a hermetic seal. An acoustic stimulus signal (e.g., a series of tones stepped from 226 Hz to 4520 Hz in 20 octave steps) are generated by the DSP chip 66 and converted to an analog signal by the D/A 68. The signal is briefly presented (i.e., on the order of milliseconds in duration) to the ear via the speaker 58. The microphone 60 transduces acoustic energy reflected off the tympanic membrane. This analog signal is filtered in a high-pass filter 70, digitized in the A/D 72, and averaged in the DSP chip 66.

The computer 74 Fourier transforms the processed signal and compares the reflected energy with the acoustic stimulus signal at each frequency. The level of sound reflected is calculated and a normalized value of the reflected signal (from 0.0 to 1.0) is plotted on the LCD screen 62 and stored in random-access-memory until the data is erased. At the completion of an AR test, the housing is placed within a well on the docking station. Electrical contacts on the base of the housing facilitate data transfer to the docking station for analysis, storage, printing, or retransmission to another computer or storage device.

To obtain OAE measurements, the speculum is inserted into the subject's ear canal. An acoustic stimulus signal is presented to the ear by the speaker. OAEs may be evoked using either transient or continuous stimulus signals. In the transient signal case, a brief click or tone burst is presented to the ear. A determination of the response signal is made by comparing the acoustic energy in the ear canal immediately following presentation of the stimulus signal with that obtained during non-stimulus periods.

In the continuous signal case, two pure tones (at frequencies f_1 and f_2) of extended duration are presented simultaneously. In a healthy ear, a response signal is re-emitted from the ear with significant energy at the cubic distortion product ($2f_1 - f_2$). These are frequently referred to as distortion product OAEs. The distortion product of the two stimulus tones is measured and compared with the energy at that frequency in the ear canal when no stimulus is presented (i.e., the continuous background "noise floor"). Any energy at the distortion product above the noise floor is due to evoked OAEs produced by the ear. The occurrence of energy in the OAE at the frequency corresponding to this cubic distortion product is a reliable test of the functional of the middle and inner ear and an extremely efficient test for use in the initial screening. Distortion product OAEs appear to be reliable predictors of hearing loss greater than 20-30 dB normal hearing level.

FIG. 5 is a block diagram of another embodiment of a portable audiometric screening apparatus configured to perform tympanometry and OAE testing. The OAE test capability is the same as described above. Tympanometry tests measure the admittance of the tympanic membrane and middle ear across a range of frequencies and over a range of pressures. To perform the test, the speculum is inserted into the ear. The speculum makes a pneumatic seal with the wall of the ear canal. An acoustic stimulus signal (e.g., user selectable combinations of pure tones at 226 Hz and 678 Hz,

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and 904 Hz), is transmitted into the ear by the speaker 58. The signal reflects off the tympanic membrane at the distal end of the ear canal and is transduced by the microphone 60. A comparison of the emitted and received signals allows a calculation of the middle ear admittance at a given pressure. The pressure in the ear canal is varied from negative to positive, relative to normal atmospheric pressure, by activating a miniature pump 76 which is located in the housing and a motor 80. A pressure transducer 78 monitors pressure in the ear. The test results are displayed on the LCD screen 62 and stored in random-access-memory until the data is erased.

The invention utilizes several acoustic stimulus signals not heretofore employed for auditory screening. For example, one or more paired tonal stimuli may be used for OAE and AEP testing. In one embodiment, a paired tonal stimulus signal includes two tones having frequencies f_1 and f_2 . To obtain OAE test results, a response signal is measured at the acoustic distortion product which corresponds to the frequency $2f_1 - f_2$. This signal has been termed the distortion product otoacoustic emission (DPOAE). For AEP tests, the response signal includes a large component corresponding to the difference in frequency between the two tones (i.e., $|f_1 - f_2|$), which is the envelope frequency of the stimulus waveform. This is termed the envelope following response (EFR).

In other embodiments, the stimulus includes multiple paired tones (e.g., f_1 and f_2 , f_3 and f_4 , f_5 and f_6). Such a signal can be used to simultaneously test at each of the frequency regions corresponding to the paired tones. For instance, if one used three paired tones of $f_1=1000$ Hz and $f_2=1040$ Hz, $f_3=3000$ Hz and $f_4=3070$ Hz, and $f_5=5000$ Hz and $f_6=5080$ Hz, hearing sensitivity can be tested simultaneously at 1000, 3000, and 5000 Hz.

A number of signal processing methods are employed in apparatuses incorporating the principles of the invention. For example, one method provides improved signal-to-noise ratio (signal-to-noise ratio) resulting in higher quality test results. For AEP and OAE tests, the evoked response (ER) is often small compared to the background noise (background noise). A high background noise level can make detection of the desired evoked response signal unreliable. A traditional solution to the signal-to-noise ratio problem has been to employ a combination of filtering, artifact rejection, and ensemble averaging. In the instant situation, the evoked response and background noise have overlapping spectra, so filtering offers only very little improvement in the signal-to-noise ratio. Artifact rejection improves the signal-to-noise by rejecting, and thereby excluding from the averaging process, sweeps which exceed some preset voltage threshold level. Sweeps which contain a large artifact (e.g., potentials resulting from brief muscle activity or loud noises such as coughing) are not included in the average if it exceeds the reject threshold level. However, it is difficult to know a priori the optimal setting for the reject level, because the background activity level is not stationary. This uncertainty limits the effectiveness of the artifact rejection technique in improving the signal-to-noise ratio. Therefore, filtering and artifact rejection techniques do not significantly increase the signal-to-noise ratio of the evoked response.

The invention utilizes an ensemble averaging technique in the time domain for improving the signal-to-noise ratio. A signal $S(t)$ is recorded (from the electrodes or ear canal microphone) that includes the desired evoked response $ER(t)$ (a deterministic signal) and background noise $BN(t)$ (a non-stationary random process). The signal $S(t)$ is averaged

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over (m) sweeps, but since the evoked response is deterministic (i.e., it does not change in amplitude, latency, or morphology over the (m) sweeps):

$$S(t)M=ER(t)M+BN(t)M \quad (1)$$

Using a signal-to-noise ratio estimate based on the evoked response/background noise ratio, and recognizing that the evoked response and background noise may not be totally uncorrelated, it can be shown that the magnitude of the averaged acquired signal $S(t)$ is a function of the signal-to-noise ratio and proportional to the magnitude of the averaged background variance. Since the magnitude of $S(t)$ is a function of the signal-to-noise ratio and background noise level, and since background noise can vary from sweep to sweep, the response signal-to-noise ratio can be maximized by expressing the variance in a single sweep or, better, in a block consisting of the average of m sweeps, relative to the estimated variance of the averaged background noise. The contribution of each block is weighted inversely to this variance ratio (i.e., individual components used in the averaging process are weighted according to their individual precision).

Using AEPs and OAEs, the foregoing is applied by assuming that (as set forth in Equation (1)) the background noise is a non-stationary, Gaussian distribution with variance changing over the course of the acquisition process. Because the acquired signal is the sum of the desired evoked response (constant) and background noise (random), the precision of an individual block average is inversely proportional to the magnitude of the signal variance. Thus, the precision of each block of sweeps, along with the subsequent weighting in the averaging process, is determined as the variance of that block relative to the estimated variance of the entire average. In one implementation, if $S(t)$ is the time waveform of the block (i.e., the average of (m) sweeps), and V is the estimated variance of the background noise after i th block, the estimate of the evoked response after the M th average will be:

$$ER_{Mth} = (S(t)_1/V_1 + S(t)_2/V_2 + \dots + S(t)_M/V_M) / (C_M^2/V_M) \text{ where } C_M^2 = 1/V_1 + 1/V_2 + \dots + 1/V_M \quad (2)$$

This estimate is obtained by adding together the averaged time waveforms from each block after dividing by their corresponding variances and multiplying this sum by $1/C_M^2$ obtained by combining all the variances, hence:

$$ER_{Mth} = 1/M [S(t)_1/V_1 + S(t)_2/V_2 + \dots + S(t)_M/V_M] / C_M \quad (3)$$

This may be contrasted with the "normal" ensemble average:

$$ER_{Mth} = 1/M [S(t)_1 + S(t)_2 + \dots + S(t)_M] \quad (4)$$

The difference is that in "normal" averaging each block is given equal weight (i.e., independent of the level of background noise level in that block), whereas in the current estimate the i th block is weighed inversely proportional to the level of the background noise in that block. When the background noise is constant across blocks, then the two estimates are identical. When the background noise varies, however, the current technique (by minimizing the contribution of noise-contaminated sweeps) yields a significantly improved estimate of the evoked response by increasing the signal-to-noise ratio.

As noted previously, the evoked response is typically buried in the background noise. Many techniques for the detection of AEPs utilize time-domain analysis of the transient evoked ABR waveform. Although detection of OAEs is typically performed in the frequency domain, only magnitude information of identified Fourier components is uti-

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lized. In the following technique, the relation between real and imaginary parts of Fourier components is fully utilized.

In steady-state AEP or OAE testing, each block of sweeps yields an evoked response to a periodic stimulus signal.

Since the evoked response is also periodic, it may be described by its Fourier components. In auditory tests measuring AEPs in response to amplitude modulated stimuli, the response at the frequency corresponding to the stimulus envelope (i.e., the EFR) is determined. Similarly, in DPOAE tests the response at the distortion component corresponding to $2f_1 - f_2$ is measured. At these frequencies, the Fourier component is a complex number z which can be expressed in a Cartesian representation $z = x + iy$. Further, the values x and y represent the cosine and sine components of the evoked response. This formulation makes explicit the notion that z is a vector in the x, y , plane. With multiple estimates of z , a cluster of vectors is built up in the complex plane. The pooled estimate of the evoked response lies in the center of the cluster, and the reliability of the pooled estimate is indicated by the degree of scatter. Estimation of the amount of scatter within the cluster should provide an index of the extent that the true evoked response may deviate from the mean of the observed response.

In audiometric tests, responses to a stimulus are collected in M blocks, with each block consisting of the average of (m) individual sweeps. Thus, a set of M estimates of the Fourier component z corresponding to the frequency of the stimulus waveform envelope is made available. To determine whether evoked response is present, it must be determined whether these estimates are consistent within an "a priori" value. The M estimates of this Fourier component can be denoted by z_1, z_2, \dots, z_M , their empirical mean value by $z_{emp} = (\sum z_i)/M$, and an "a priori" hypothetical value by ξ . Each of the quantities z_i , z_{emp} and ξ are complex numbers, decomposable into real and imaginary parts: $z_i = x_i + iy_i$; $z_{emp} = x_{emp} + iy_{emp}$; and $\xi = \xi_r + i\xi_i$. From the scatter of individually determined components z_i about their mean, with each of the deviations $x_i - x_{emp}$ and $y_i - y_{emp}$ providing one estimate, an estimate of the individual population variance is made:

$$V_{ind} = \frac{1}{M} \sum_{i=1}^M [(x_i - x_{emp})^2 + (y_i - y_{emp})^2] = \frac{1}{M} \sum_{i=1}^M |z_i - z_{emp}|^2 \quad (5)$$

which is independent of the assumed population mean ξ .

A second estimate, referred to as the group variance, is dependent on ξ . Because the real and imaginary parts of z_{emp} are independently distributed and unconstrained by V_{ind} , a second group variance estimate is as follows:

$$V_{group} = \frac{1}{M} \sum_{i=1}^M [(x_i - \xi_r)^2 + (y_i - \xi_i)^2] = \frac{1}{M} \sum_{i=1}^M |z_i - \xi|^2 \quad (6)$$

The estimate of the Fourier component for each block of (m) samples, z_i , are subsamples of a population whose mean is ξ , and the quantities V_{ind} and V_{group} are estimates of the overall variance derived from independent quantities. Therefore, the ratio V_{group}/V_{ind} is distributed according to the F distribution. Based on this variance ratio, a statistical approach is utilized wherein:

$$R = \frac{1}{M} \sum_{i=1}^M (V_{group}/V_{ind}) \sim (M-1, 1) \left(\frac{\xi_r^2 + \xi_i^2}{2} \right) \quad (7)$$

Therefore, for M independent estimates of Fourier components z_i drawn from a sample of assumed mean ξ , MOR is distributed according to $F_{[2, 2M-2]}$.

This statistic, unlike other methods, fully utilizes the independence of the real and imaginary parts of the Fourier component of interest and is used for detecting the presence of a response by determining if the observed set of Fourier components z_i at the frequency corresponding to the stimulus envelope or cubic distortion product, is consistent with random fluctuations alone (i.e., no response signal), or whether the set of observations implies, to within a given confidence level, that a response component is present.

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In conducting audiometric studies using AEPs or OAEs, a standard procedure has been to specify that a fixed number of sweeps be acquired. However, as noted above, in situations in which the subject is quiet, with relatively low background noise, or when the stimulus is considerably above threshold, a large evoked response will be recorded with a correspondingly high signal-to-noise ratio. Thus, only relatively few sweeps are required to obtain an acceptable response. Alternatively, in situations where the subject is noisy (either episodic or during an entire test session), or where the stimulus is close to threshold, then the response is smaller or buried in larger noise, with a resultant lowered signal-to-noise ratio. In these conditions, a large number of sweeps may be required. If the artifact rejection threshold is set sufficiently low to exclude such episodic noise, or if the subject displays a sustained period of relatively high noise level, then no sweeps need be added to the accumulating buffer for averaging. By lowering the reject threshold, fewer noise-contaminated sweeps are included in the average (yielding in a higher signal-to-noise ratio), but this is at a cost of greatly prolonging the test time required to achieve a preset number of sweeps. The specification of a fixed number of sweeps is clearly an inefficient approach. In some instances, the number may be excessive (needlessly prolonging the test) or insufficient (thereby yielding an unacceptably low signal-to-noise ratio). It is quite difficult to predict "a priori" the number of sweeps required to achieve a given signal-to-noise ratio just as it is quite difficult to preset an optional artifact rejection level. However, a "a priori" the number of sweeps required to achieve a given signal-to-noise ratio just as it is quite difficult to preset an optional artifact rejection level. However, a means to estimate the quality of the obtained evoked response on an ongoing basis is available from the variances already calculated. The ratio of the variance of the averaged response block to the estimated variance of the ongoing background noise can be treated as an F-distribution:

$$F_s = \text{VAR}(ER(i)) / \text{VAR}(N(i)) \quad (8)$$

In automating the test, stimulus presentation and response acquisition continues until a prespecified criterion value for acceptance is met.

The signal processing described above, although widely applicable for use with a variety of stimulus signal types, is particularly useful in facilitating acquisition and detection of responses using DPOAE and EFR tests described above. The hardware and software of the present system makes possible the acquisition and automated detection of both DPOAEs and AEPs simultaneously.

EQUIVALENTS

While the invention has been particularly shown and described with reference to specific preferred embodiments, it should be understood by those skilled in the art that various changes in form and detail may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

I claim:

1. An audiometric apparatus comprising:

- a probe insertible in a subject's ear, the probe including (i) a transmitter for transmitting a first stimulus signal into the subject's ear and (ii) a receiver for receiving a first response signal from the subject's ear;
- an electrode attachable to the subject's scalp for sensing a second response signal from the subject's scalp; and
- a signal processor electrically coupled to the probe and the electrode for processing the first response signal to

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provide an evoked otoacoustic emission signal and processing the second response signal to provide an auditory evoked potential signal.

- 2. The apparatus of claim 1 wherein the first stimulus signal comprises an amplitude modulated signal.

- 3. The apparatus of claim 1 wherein the first stimulus signal comprises at least one paired tonal stimuli.

- 4. The apparatus of claim 1 wherein the signal processor processes the first and second response signals in parallel.

- 5. The apparatus of claim 4 wherein the signal processor processes the first and second response signals simultaneously.

- 6. The apparatus of claim 1 wherein the transmitter transmits a second stimulus signal into the subject's ear, the receiver receives a third response signal from the subject's ear, and the signal processor processes the third response signal to provide an acoustic reflectivity signal.

- 7. The apparatus of claim 1 wherein the first stimulus signal comprises a transient signal.

- 8. The apparatus of claim 1 further comprising:

- a digital signal processing element;

- a memory electrically coupled to the digital signal processing element;

- a digital-to-analog converter electrically coupled to the digital signal processing element for converting the first stimulus signal from a digital format into an analog format;

- an attenuator electrically coupled to the digital-to-analog converter for regulating the first stimulus signal;

- a filter electrically coupled to the receiver and the electrode for filtering the first and second response signals;

- an analog-to-digital converter electrically coupled to the filter for converting the first and second response signals from an analog format into a digital format for the digital signal processing element.

- 9. The apparatus of claim 8 further comprising:

- a first amplifier electrically coupled to the probe for providing amplified first response signals to the filter; and

- a second amplifier electrically coupled to the electrode for providing amplified second response signals to the filter.

- 10. The apparatus of claim 1 further comprising:

- a control processor for requesting an evoked otoacoustic emission signal and an auditory evoked potential signal;

- a display electrically coupled to the control processor for displaying one or more characteristics of the evoked otoacoustic emission signal and the auditory evoked potential signal; and

- an input device electrically coupled to the control processor to enable a user to request the evoked otoacoustic emission signal and the auditory evoked potential signal.

- 11. An auditory signal processing method comprising:

- inserting a probe in a subject's ear;

- transmitting a stimulus signal into the subject's ear via the probe;

- receiving a response signal from the subject's ear; and averaging the response signal over a plurality of intervals to produce a plurality of subaverages;

- inversely weighting each subaverage; and

- combining the inversely weighted subaverages to produce an auditory indication signal.

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12. The method of claim 11 wherein the auditory indication signal is an evoked otoacoustic emission signal and or an auditory evoked potential signal.

13. The method of claim 11 wherein the stimulus signal comprises an amplitude modulated signal or a transient signal.

14. The method of claim 11 further comprising inversely weighting each subaverage based the variance and content of the response signal.

15. The method of claim 11 wherein the combining step comprises averaging the inversely weighted subaverages to produce an auditory indication signal.

16. The method of claim 15 wherein the combining step comprises:

performing a Fourier transform for each subaverage; determining real and imaginary components of the Fourier transform at specified frequencies; independently estimating variance of each component; and

determining the probability of an auditory indication signal using an F statistic.

17. A bioelectrical signal processing method comprising:

attaching a sensor to a subject; transmitting a stimulus signal into the subject; receiving a response signal from the subject via the sensor; and

averaging the response signal over a plurality of intervals to produce a plurality of subaverages;

inversely weighting each subaverage; and combining the inversely weighted subaverages to produce a bioelectrical signal.

18. The method of claim 17 wherein the sensor is an electrode.

19. The method of claim 17 wherein the sensor is a probe.

20. The method of claim 17 wherein the bioelectrical signal is an auditory signal.

21. The method of claim 20 wherein the auditory indication signal is an evoked otoacoustic emission signal and or an auditory evoked potential signal.

22. The method of claim 17 wherein the stimulus signal comprises an amplitude modulated signal.

23. The method of claim 17 wherein the stimulus signal comprises a transient signal.

24. The method of claim 17 further comprising inversely weighting each subaverage based the variance and content of the response signal.

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25. The method of claim 17 wherein the combining step comprises averaging the inversely weighted subaverages to produce the bioelectrical signal.

26. The method of claim 25 wherein the combining step comprises:

performing a Fourier transform for each subaverage; determining real and imaginary components of the Fourier transform at specified frequencies; independently estimating variance of each component; and

determining the probability of the bioelectrical signal using an F statistic.

27. An automated bioelectrical signal processing method comprising:

a) attaching a sensor to a subject; b) transmitting a stimulus signal into the subject; c) receiving a response signal from the subject via the sensor; and

d) averaging the response signal over a plurality of intervals to produce a plurality of subaverages;

e) inversely weighting each subaverage;

f) performing a Fourier transform for each subaverage;

g) determining real and imaginary components of the Fourier transform at specified frequencies;

h) analyzing the components to determine the presence of (1) a bioelectrical signal and random noise, or (2) only random noise; and

i) repeating steps b) to h) if the components are indicative of only random noise.

28. A signal processing apparatus comprising:

a probe insertible in a subject's ear, the probe including (i) a transmitter for transmitting a first stimulus signal and a second stimulus signal into the subject's ear, and

(ii) a receiver for receiving a first response signal and a second response signal from the subject's ear; and

a signal processor electrically coupled to the probe for processing the first response signal to provide an evoked otoacoustic emission signal and processing the second response signal to provide an auditory indication signal.

29. The apparatus of claim 28 wherein the auditory indication signal is a tympanometry signal or an acoustic reflectivity signal.

* * * * *

EXHIBIT C



US006832663B2

(12) United States Patent
Warring et al.**(10) Patent No.: US 6,832,663 B2**
(45) Date of Patent: Dec. 21, 2004**(54) EAR COUPLER****(75) Inventors:** Jessica Ash Warring, San Carlos, CA (US); Alfred Christian Walton, Belmont, CA (US)**(73) Assignee:** Natus Medical Inc., San Carlos, CA (US)**(*) Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.**(21) Appl. No.:** 09/941,132**(22) Filed:** Aug. 27, 2001**(65) Prior Publication Data**

US 2003/0037988 A1 Feb. 27, 2003

(51) Int. Cl.⁷ H04R 25/00**(52) U.S. Cl.** 181/129**(58) Field of Search** 181/129, 130, 181/132, 134, 135, 136, 137**(56) References Cited****U.S. PATENT DOCUMENTS**

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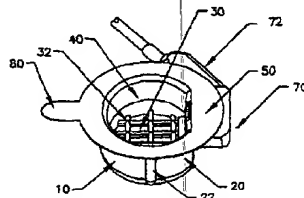
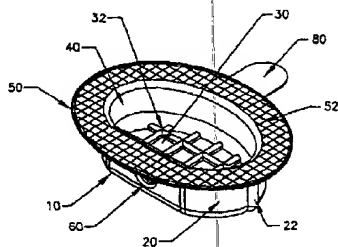
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GB 2010640 A 6/1979

* cited by examiner

Primary Examiner—Kimberly Lockett*(74) Attorney, Agent, or Firm*—Daniel P. Maguire**(57)****ABSTRACT**

A one-piece, transparent flexible ear coupler for use with hearing evaluation is disclosed. It includes an annular side wall and a bottom wall forming an acoustic chamber. A flexible adhesive-backed flange is disposed on the periphery of the ear coupler. The flange attaches to the subject's head, firmly holding the ear coupler in place over the ear. The annular side wall has a port for the placement of a transducer assembly, and also has ribs to help lock the transducer assembly in place. The transducer assembly can be placed in an up or down position, and can be switched between positions while the coupler is attached to the subject's head. The ear coupler advantageously conforms to the subject's head, thereby minimizing the likelihood that the ear coupler will become detached during testing. The coupler can be inexpensively manufactured, since its one-piece design allows the use of relatively low-cost processes such as injection molding and thermoforming.

28 Claims, 6 Drawing Sheets

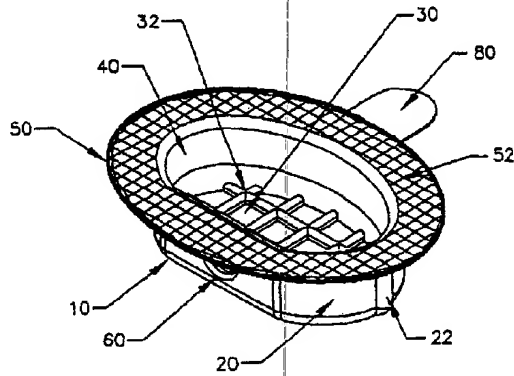


Figure 1

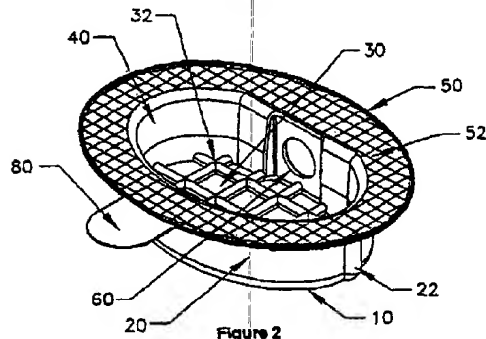


Figure 2

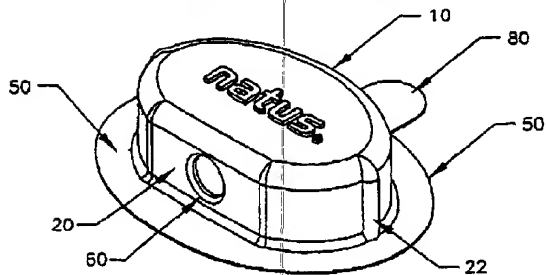
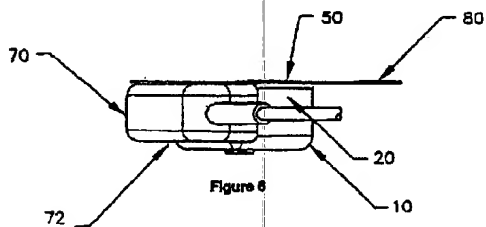
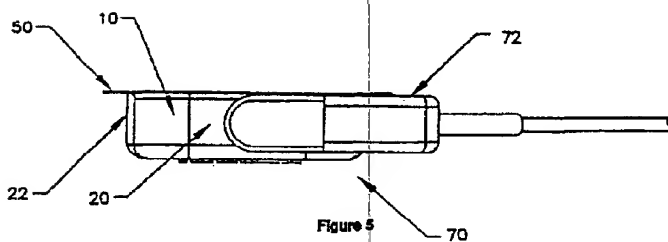
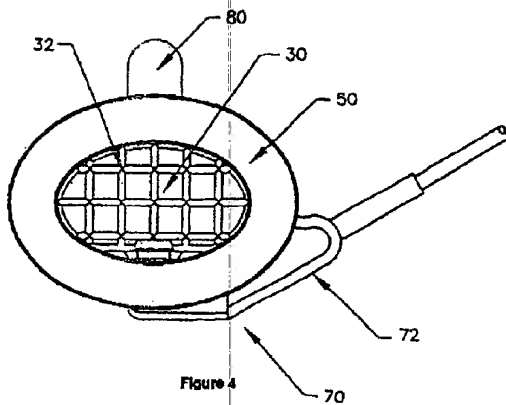


Figure 3



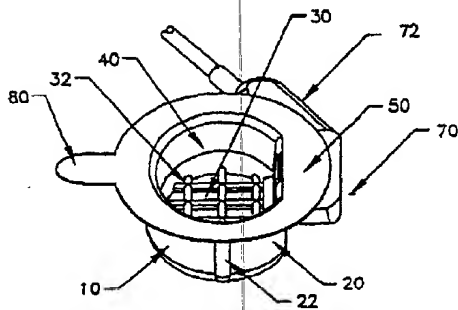


Figure 7

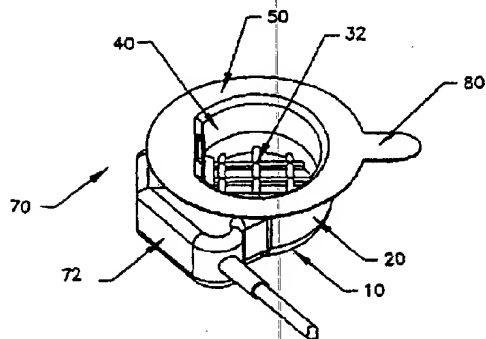


Figure 8

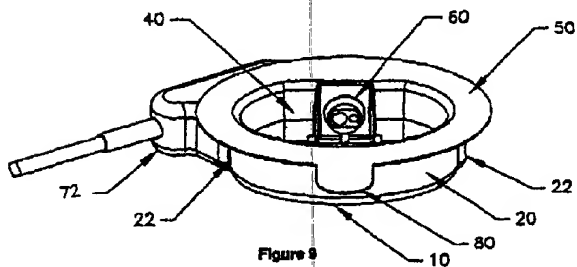


Figure 9

1 8. On December 21, 2004, the United States Patent and Trademark Office duly
2 and lawfully issued U.S. Patent No. 6,832,663 ("the '663 patent"), titled "Ear Coupler." Natus
3 owns the '663 patent by assignment. A copy of the '663 patent is attached hereto as Exhibit
4 C

5 9. Natus has marked its competing product, the Flexicoupler, which it has
6 manufactured and sold under the '663 patent with the number of the '663 patent in
7 accordance with 35 U.S.C. § 287(a).

8 **CLAIM 1: CLAIM FOR INFRINGEMENT OF**

9 **U.S. PATENT NO. 5,601,091 BY IHS**

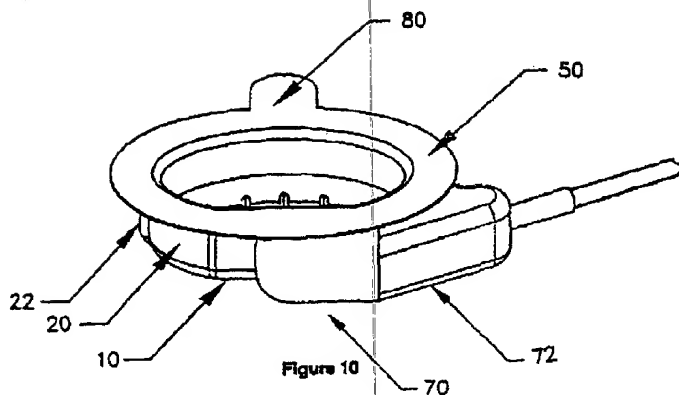
10 10. Natus repeats, realleges and incorporates by reference the allegations set forth
11 in paragraphs 1-9 of this Complaint.

12 11. This is a claim for patent infringement arising under the patent laws of the
13 United States, Title 35 of the United States Code.

14 12. Without authority, IHS, through its agents, employees and servants, has
15 manufactured, used, promoted, offered for sale, and/or sold within the United States, and/or
16 imported into the United States products covered by one or more claims of the '091 patent, has
17 actively induced others to do the same and/or has contributed to others' performance of the
18 same. IHS has thereby infringed, actively induced others to infringe and/or contributed to
19 others' infringement of one or more claims of the '091 patent in violation of 35 U.S.C. § 271,
20 including 35 U.S.C. §§ 271(a), (b) and/or (c). This infringement is currently ongoing. The
21 products relating to IHS's infringement includes the SmartScreener Plus-2 product.

22 13. Upon information and belief, IHS has derived, received, and will continue to
23 derive and receive gains, profits and advantages from the aforesaid acts of infringement of the
24 '091 patent in an amount that is not presently known to Natus. Due to the infringement of the
25 '091 patent by IHS, Natus has been damaged and is entitled to monetary relief in an amount to
26 be determined at trial.

27 14. Unless IHS is enjoined from infringing the '091 patent, Natus will continue to
28 suffer irreparable injury for which it has no adequate remedy at law.



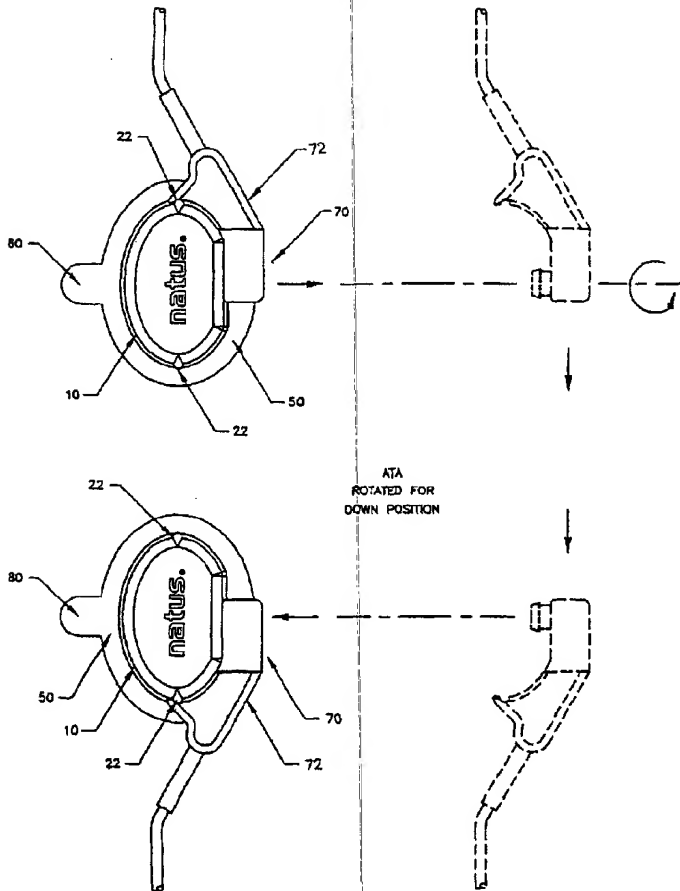


Figure 11

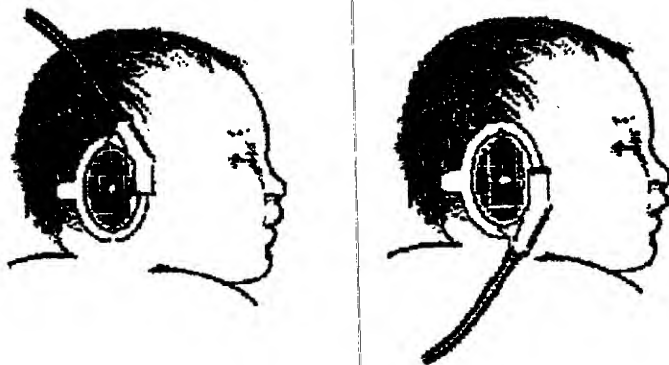


Figure 12

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EAR COUPLER

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to ear couplers or earphones that cover the ear to create a desired acoustic environment.

2. Background of the Invention

It is inherently difficult to determine hearing impairment in infants, since they cannot participate in traditional hearing tests which require subjects to indicate whether they can hear various sounds. However, if hearing impairment is not detected until the infant grows into a toddler or child, then the potential for long-term disability increases, since the child's language skills will have developed before remedial measures have been undertaken. The optimal time to screen for hearing impairment is immediately after birth, both because early detection allows for early treatment, and because parents often fail to bring their children in for later appointments.

Devices and methods have been developed to evaluate infant hearing by subjecting an infant to an aural stimulus, and then measuring the electroencephalographic or otoacoustic response to that stimulus. These devices and methods depend on the creation of the proper acoustic environment about the subject's ear, so that ambient noise does not interfere with the hearing evaluation, and so that the stimulus has the appropriate duration, amplitude, and frequency content.

To create the desired acoustic environment, earphones or ear couplers have been used. Information relevant to previous ear couplers can be found in U.S. Pat. Nos. 5,826,582, 4,930,520, and in U.S. patent application Ser. No. 09/395,799. Although many of these devices have worked well, they can sometimes become detached from the subject's head, because of the variable and irregular surfaces surrounding the ear, and because infants tend to move during testing. Additionally, with previous ear couplers, the assembly that houses the stimulus-producing transducer tends to tug the ear coupler away from the ear. Existing ear couplers are also relatively expensive to manufacture, in part because they require production or assembly of more than one part.

It is therefore desirable to construct an ear coupler that is better able to remain attached to the subject's head, and that is not subject to being tugged off the head by forces acting on the transducer housing. It is also desirable to design a one-piece ear coupler that can be inexpensively manufactured by injection molding or other suitable processes.

BRIEF SUMMARY OF THE INVENTION

The present invention is a transparent one-piece ear coupler, with an internal chamber that creates a tuned acoustic environment about the subject's ear, with a port to accommodate a transducer, and with a flange positioned around the periphery of the coupler to attach the coupler to the subject's head.

Other features of the preferred embodiment of the present invention include a tab to facilitate removal of the ear coupler, and a mark or target on the coupler to help ensure proper alignment over the subject's ear. The coupler is generally D-shaped, and is designed so as to fit on either ear. Preferably, the coupler is made of transparent Rimflex® thermoplastic elastomer, although other flexible, transparent materials could be used. The bottom wall of the coupler contains waffle-shaped or other surface features, which add rigidity and create the desired acoustic characteristics of the chamber.

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The exterior wall of the coupler is ribbed to provide means to securely lock in place the housing that contains the transducer. The side of the flange in contact with the skin contains hydrogel or another adhesive substance to stick to the subject's head. The interior surface of the flange may also contain waffle-shaped or other surface features for improved adhesion of the hydrogel to the Rimflex®, although no such extrusions are provided in the preferred embodiment of this invention. The walls of the coupler are of sufficient thickness to resist crushing, and to provide the desired acoustic environment about the subject's ear.

The housing that contains the transducer, known as an acoustic transducer assembly (ATA), securely and positively fits into the port that enters into the internal chamber. The ATA latches onto ribs on the sides of the coupler, and can be rotated up or down while in use, so that the length of the ATA can be placed either above or below the center of the coupler.

Before being attached to the subject's head, the ear couplers are attached to release paper. Preferably, the adhesive that secures the ear couplers to the release paper (and to the subject's head) is a hydrogel, which can be selectively applied only to the flange of the ear coupler during manufacture, thereby minimizing waste. There are holes in the release paper, centered over the chamber of the ear coupler, to help the user hold the coupler while the ATA is being inserted.

In operation, the ATA is inserted into the port, and the ear coupler is removed from the release paper and placed on the subject's ear. The adhesive on the flange sticks to the subject's head, and because of the unique features of the invention as disclosed herein, the ear coupler will tend to stay affixed to the infant's head, even if he or she moves during testing. The tab helps remove the ear coupler from the release paper, and helps remove it from the subject's head when the testing is complete.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevated perspective view of the ear coupler in accordance with a preferred embodiment of the present invention.

FIG. 2 is an elevated perspective view of the ear coupler in accordance with a preferred embodiment of the present invention, from the opposite side as FIG. 1.

FIG. 3 is a bottom elevated perspective view of the ear coupler in accordance with a preferred embodiment of the present invention.

FIG. 4 is a top plan view of the ear coupler in accordance with a preferred embodiment of the present invention, with the ATA.

FIG. 5 is a side view of the ear coupler with the ATA in accordance with a preferred embodiment of the present invention.

FIG. 6 is a side view, from a different perspective than FIG. 5, of the ear coupler with the ATA in accordance with a preferred embodiment of the present invention.

FIG. 7 is an elevated side perspective view of the ear coupler in accordance with a preferred embodiment of the present invention, with the ATA.

FIG. 8 is an elevated side perspective view of the ear coupler in accordance with a preferred embodiment of the present invention, with the ATA, from the opposite perspective of FIG. 7.

FIG. 9 is an elevated perspective view of the ear coupler in accordance with a preferred embodiment of the present invention, with the ATA.

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FIG. 10 is an elevated perspective view of the ear coupler in accordance with a preferred embodiment of the present invention, with the ATA, from the opposite perspective of FIG. 9.

FIG. 11 shows movement of the ATA between the up and down positions.

FIG. 12 shows the ear coupler in accordance with a preferred embodiment of the present invention being worn by an infant, with the ATA in both the up and down positions.

DETAILED DESCRIPTION

The present invention comprises a one-piece, transparent ear coupler body, 10, with an annular side wall, 20, a bottom wall, 30, an internal chamber, 40, a peripheral flange, 50, a port, 60, an ATA, 70, and a tab, 80. Various aspects and features of the preferred embodiment of this invention are described below.

The ear coupler body, 10, is generally D-shaped, and sized to fit an infant's ear. It is made of a flexible, transparent, smooth, non-crumbly, nonporous material, preferably Rimflex®, which is available from Bay State Polymer Distribution, Inc., P.O. Box 40055, Bay Village, Ohio 44140. Other suitable materials include Kraton, PVC, polyurethane, and Engage. By using a transparent material, the ear coupler can more easily and accurately be placed over the subject's ear. Opaque materials can be used to create the desired acoustic environment, but they do not allow the clinician to visualize the placement of the coupler over the center of the subject's ear.

Preferably, the ear coupler is comprised of one-piece, which may result in lower manufacturing costs compared with multi-piece couplers. However, the coupler can be composed of more than one piece, so long as the pieces or their connections are flexible enough so that ear coupler can accommodate the irregular and curved shape of a subject's head. The ear coupler can be made by injection molding, thermoforming, and other processes. The ear coupler is not "handed," meaning that it can fit on either the right or left ear. The ear coupler is provided clean, and can be sterilized as needed for certain applications. The ear coupler is designed to be disposable.

The annular side wall, 20, forms a ring around the internal portion of the ear coupler. Preferably, the annular side wall forms a D-shaped ring, although other shapes could be used. The D-shape helps to orient placement of the coupler, so that it is placed with the ATA providing the stimulus from the front of the ear. The annular side wall contains two or more ribs, 22, that are used to removably latch the ATA in place, as described below.

The annular side wall should be thick enough to provide crush resistance, and in the preferred embodiment is approximately 1/4th of an inch thick. Ribs, 22, can also be used to improve crush resistance, but in the preferred embodiment, the annular side wall provides sufficient strength on its own. The annular side wall is of uniform thickness, except around the port, 60, where it is substantially thinner in order to help create the interference fit as described below.

The bottom wall, 30, is attached to or integral with the annular side wall. Like the annular side wall, the bottom wall is thick enough to resist crushing when the subject lies on his or her ear. In the preferred embodiment, the bottom wall is approximately 1/8th of an inch thick.

To improve the acoustics of the ear coupler, the surface (exterior or interior) of the bottom wall contains a pattern of

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surface features, 32. Preferably, these surface features are a pattern of cross-hatched protuberances that create a waffle-type surface. These surface features add strength and rigidity to the bottom wall, and prevent it from vibrating in response to the stimulus. If the bottom wall were subject to vibration, then the ear coupler would create different acoustic environments based on whether the bottom wall was under pressure or not. For instance, if the subject were lying on his or her back, then the bottom wall could vibrate, but if the subject were lying on his or her side, then the ear coupler could be pressed against the bed, thereby inhibiting vibration. By adding the surface features, the ear coupler is not subject to any such vibration regardless of the subject's position, and thus the ear coupler creates the consistent and predictable acoustic environment needed for accurate hearing screening.

The bottom wall also preferably includes a target indicating the center of the coupler, to help facilitate proper placement of the coupler over the subject's ear. The bottom wall could also be imprinted with text, such as the name or trademark of the company manufacturing or selling the ear coupler.

The chamber, 40, is formed by the annular side wall and the bottom wall, and is sufficiently large to accommodate the subject's ear. The chamber creates a tuned, isolated acoustic chamber, with precise acoustic properties so that hearing screening can be conducted. Aural stimuli are transmitted into the chamber through the port.

The flange, 50, extends around the periphery of coupler, projecting out past the annular side wall. The flange may be centered over the internal chamber, or can begin at the annular side wall. The flange can be cut or slit to increase its ability to conform to the subject's head, and indeed, multiple flanges could be used. In the preferred embodiment, as reflected in the drawings, a single unitary flange beginning at the annular side wall is used. The flange should be flexible, so that it can securely attach to the curved and irregular shape of a subject's head.

The flange is relatively planar or smoothly tapered, but may have barriers at the inner and outer periphery to help contain the adhesive. In the preferred embodiment, these barriers take the form of slight ridges that prevent overflow when the flange is coated with adhesive during manufacture.

The preferred adhesive is hydrogel, although other adhesives could be used so long as they allow the coupler to be removably attached to the subject's head. Previous ear couplers have used a laminate for adhesion, which resulted in wasted material, since the adhesive pattern had to be punched from a sheet of hydrogel material. Under the present invention, the hydrogel is selectively applied only to the flange, and then placed on the release paper, resulting in minimal waste.

The flange, coated with adhesive, is the preferred structure to removably attach the ear coupler to the subject's head. However, if a flange is not used, then the ear coupler could be attached to the subject's head by any number of conventional means, such as tape, clips, a headband, or adhesive applied to the periphery of the coupler or to a flexible extension attached to the periphery.

The hydrogel may have a pattern of surface features, 52, on the surface that contacts the infant's head. These surface features may improve adhesion of the flange to the Rimflex®, although they are not present in the preferred embodiment of this invention.

The flange extends from the annular side wall a sufficient distance for proper adhesion. In a preferred embodiment of

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present invention, the flange extends approximately $\frac{1}{4}$ inch from the annular side wall.

The port, 60, is an opening in the annular side wall for placement of the ATA, 70. Preferably, the port is sized to create an interference fit with the ATA, so that there is some initial resistance when placing the ATA in the port, and then there is a click or snap when the ATA is pushed into place. For purposes of this patent, "interference fit" denotes the fit between the ATA and the port, whereby there is initial resistance and then relief once the ATA snaps into place. The tip of the ATA is barbed to facilitate insertion into the port. Preferably, when placed on the infant's head, the port will face the front or tragus side of the infant's ear, which corresponds to the flat portion of the "D" shaped coupler.

The ATA, 70, is an assembly that houses a transducer for generating the aural stimuli. It also may house other devices such as a microphone for monitoring acoustic energy within the environment. The ATA is on the end of a cable, which connects it to the hearing evaluation device. The ATA snaps into the port, and may be positioned in either an up or a down position, along the side of the ear coupler, as illustrated in FIGS. 11 & 12. The ATA can be rotated between the up and down positions during screening, as shown in FIGS. 11 and 12. The ATA also may include a latch that snaps onto the ribs of the annular side wall, helping to ensure that the ear coupler is not tugged away from the subject's head. The ATA hugs or mates with the side of the ear coupler, which improves crush resistance and prevents the ATA from acting as a lever which could pull the ear coupler off the subject's head. More specifically, the ATA has an arm 72 that extends laterally away from the port 60 when the ATA 70 is placed into the port 60. See FIGS. 4, 7, 8, 9, 10, and 11.

The tab, 80, is attached to or integral with the flange, and is used to help remove the ear coupler from the infant's head. Preferably, the tab, 80, is placed opposite to the port, 60, but could be placed anywhere on the periphery of the flange. The tab is also useful in removing the ear coupler from the release paper.

Before use, the ear coupler is provided to the user attached to release paper, to help ensure cleanliness and to preserve the sticking power of the adhesive. Holes may be placed in the portion of the release paper facing the bottom wall, to make it easier to hold the coupler while inserting the ATA.

In operation, the ATA, 70, is inserted into the port, 60, and snapped onto the ribs in either the up or down position, depending on the operator's preference. The ear coupler, 10, is then removed from the release paper and placed on the subject's head, so as to cover his or her ear. The adhesive on the flange, 50, holds the coupler in place during testing. As necessary, the ATA can be flipped from the up or down position during testing to accommodate the particular position of the subject. After testing, the ear coupler is removed, using the tab.

The present ear coupler is much less likely to become detached during testing than previous couplers, since its flexible, one-piece body can better accommodate the irregular and curved shape of the subject's head. It also is better able to move and stretch as necessary in response to the subject's movements.

The present ear coupler is also less costly to manufacture, since it is preferably made of one-piece, and can be created using relatively inexpensive processes such as injection molding and thermoforming.

The ear coupler can be used for hearing screening of infants, children, or adults, and can also be used as a sound-blocking "ear muff," when a quiet acoustic environment is desired.

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One skilled in the art will appreciate that the present invention can be practiced by other than the described embodiments, which are presented for purposes of illustration and not limitation. The particular dimensions and materials recited herein are presented for purposes of illustration and not limitation.

We claim:

1. An ear coupler comprising:

an annular side wall;
a bottom wall, integral with said annular side wall;
an internal chamber, formed by said bottom wall and said annular side wall;
a port in said annular side wall; and
a highly flexible flange extending from and substantially around said annular side wall.

2. The ear coupler of claim 1, wherein said annular side wall and said bottom wall are transparent.

3. The ear coupler according to claim 1 or 2, additionally comprising ribs in said annular side wall.

4. The ear coupler according to claim 1 or 2, wherein said bottom wall contains surface features.

5. The ear coupler according to claim 1 or 2, wherein said bottom wall contains a target to aid in placing the coupler over the subject's ear.

6. The ear coupler according to claim 1 or 2, wherein said highly flexible flange is coated with adhesive, and wherein said highly flexible flange includes a barrier for containment of said adhesive.

7. The ear coupler according to claim 6, wherein said highly flexible flange additionally includes a second set of surface features to aid in coating said highly flexible flange with said adhesive.

8. The ear coupler according to claim 1 or 2, additionally comprising an acoustic transducer assembly adapted to removably fit in said port.

9. The ear coupler according to claim 8, wherein there is an interference fit between said acoustic transducer assembly and said port.

10. The ear coupler according to claim 9, wherein when said acoustic transducer assembly is fitted in said port, the acoustic transducer assembly mates with the ribs in said annular side wall.

11. The ear coupler according to claim 10, wherein said acoustic transducer assembly can mate in either an up or down position with said ribs in said annular side wall.

12. The ear coupler according to claim 11, wherein said acoustic transducer can be switched between mating positions during use.

13. The ear coupler according to claim 1 or 2, additionally comprising a tab integral with said highly flexible flange.

14. An ear coupler comprising:

an annular sidewall;
a bottom wall, integral with said annular side wall;
an internal chamber, formed by said bottom wall and said annular side wall;
a port in said annular side wall; and
a highly flexible flange extending from and substantially around said annular side wall, said flange being coated with adhesive, and having a barrier for containment of said adhesive.

15. An ear coupler comprising a one-piece body, said body having:

an internal chamber,
a port in communication with said chamber,
a highly flexible flange, coated with adhesive, disposed around said chamber, wherein said body is made by injection molding or thermoforming.

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16. The ear coupler according to claim 15, wherein said body is transparent.

17. The ear coupler according to claim 15, additionally comprising a tab integral with said highly flexible flange.

18. The ear coupler according to claim 16, additionally comprising a target to aid in placing the coupler over the subject's ear.

19. An ear coupler comprising:

an annular side wall;

a bottom wall, integral with said annular side wall;

an internal chamber, formed by said bottom wall and said annular side wall;

a port in said annular side wall for receiving an acoustic transducer assembly, said port sized so as to create an interference fit with said acoustic transducer assembly; and

a means for removably attaching the ear coupler to a subject's head.

20. An ear coupler comprising:

an annular side wall;

a bottom wall, connected with said annular side wall;

an internal chamber, formed by said bottom wall and said annular side wall;

a port in said annular side wall; and

a highly flexible flange connected with and substantially circumscribing said annular side wall, said flexible flange being coated with an adhesive for attaching the ear coupler to a subject's head.

21. An ear coupler comprising:

an annular side wall;

a bottom wall, integral with said annular side wall;

an internal chamber, formed by said bottom wall and said annular side wall;

a port in said annular side wall; and an acoustic transducer assembly adapted to mate with said annular side wall in an either up or down position.

22. A method for assembling an ear coupler, comprising the steps of:

providing a one-piece transparent body, said body having an annular side wall, a bottom wall, and a highly flexible flange;

defining a port for entry of an acoustic transducer assembly in said annular side wall; and dispensing an adhesive on said highly flexible flange.

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23. The method according to claim 22, additionally comprising providing for surface features in said bottom wall.

24. The method of claim 23, additionally comprising providing for ribs in said annular side wall.

25. An ear coupler assembly comprising:

an annular side wall;

a bottom wall, attached to said annular side wall;

an internal chamber, formed by said bottom wall and said annular side wall;

a port in said annular side wall, said port having a longitudinal axis extending into and out of said port; and

an acoustic transducer assembly capable of being releasably attached to said port so that a portion of said assembly extending from said port is generally perpendicular to said longitudinal axis.

26. A method of preparing an ear coupler for use in hearing evaluation, comprising:

providing an ear coupler assembly according to claim 25; and

attaching said acoustic transducer assembly to said port so that a portion of said acoustic transducer assembly is generally perpendicular to said longitudinal axis.

27. An ear coupler assembly comprising:

an annular side wall;

a bottom wall, attached to said annular side wall;

an internal chamber, formed by said bottom wall and said annular side wall;

a port in said annular side wall; and

an acoustic transducer assembly, wherein said acoustic transducer assembly has an arm, and wherein said arm extends laterally away from said port when said acoustic transducer assembly is fitted in said port.

28. A method of preparing an ear coupler for use in hearing evaluation, comprising:

providing an ear coupler assembly according to claim 27; and

attaching said acoustic transducer assembly to said port so that said arm extends laterally away from said port.

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1 22. Without authority, IHS, through its agents, employees and servants, has
2 manufactured, used, promoted, offered for sale, and/or sold within the United States, and/or
3 imported into the United States products covered by one or more claims of the '663 patent, has
4 actively induced others to do the same and/or has contributed to others' performance of the
5 same. IHS has thereby infringed, actively induced others to infringe and/or contributed to
6 others' infringement of one or more claims of the '663 patent in violation of 35 U.S.C. § 271,
7 including 35 U.S.C. §§ 271(a), (b) and/or (c). This infringement is currently ongoing. The
8 products relating to IHS's infringement includes the Earhug product.

9 23. Upon information and belief, IHS has derived, received, and will continue to
10 derive and receive gains, profits and advantages from the aforesaid acts of infringement of the
11 '663 patent in an amount that is not presently known to Natus. Due to the infringement of the
12 '663 patent by IHS, Natus has been damaged and is entitled to monetary relief in an amount to
13 be determined at trial.

14 24. Unless IHS is enjoined from infringing the '663 patent, Natus will continue to
15 suffer irreparable injury for which it has no adequate remedy at law.

16 **PRAYER FOR RELIEF**

17 Natus respectfully prays for:

18 A. An order adjudging IHS to have infringed each of the '091, '174 and '663
19 patents;

20 B. A permanent injunction enjoining IHS, as well as its officers, agents, servants,
21 employees, and attorneys and those persons in active concert or participation with IHS, from
22 infringing the '091, '174 and '663 patents;

23 C. An accounting of all gains, profits, and advantages derived by IHS's
24 infringement of the '091, '174 and '663 patents and an award of damages adequate to
25 compensate Natus for IHS's infringement of the '091, '174 and '663 patents;

26 D. An award of pre-judgment and post-judgment interest and costs of this action
27 against IHS;

28 ///

- 1 E. An award to Natus of its attorneys' fees incurred in connection with this action;
2 and
3 F. Such other and further relief as the Court deems just and proper.
4

5 Respectfully submitted,

6 KNOBBE, MARTENS, OLSON & BEAR, LLP
7

8
9 Dated: 2-18-2010

By: Stephen C. Jensen

10 Stephen C. Jensen
11 Joseph R. Re
12 Jarom D. Kesler

13 Attorneys for Plaintiff
14 NATUS MEDICAL INCORPORATED
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1 **DEMAND FOR JURY TRIAL**

2 Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff Natus
3 Medical Incorporated hereby demands a trial by jury on all issues so triable.
4

5 Respectfully submitted,

6 KNOBBE, MARTENS, OLSON & BEAR, LLP
7

8
9 Dated: 2-18-2010

By:

Stephen C. Jensen
Stephen C. Jensen
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10 Attorneys for Plaintiff
11 NATUS MEDICAL INCORPORATED
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EXHIBIT A